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Extended EHR@EU Data Space for Primary Use - Xt-EHR

Proposal number: 101128085

EHDS Guidelines for manufacturers of wellness applications

"D8.3 – Wellness application labelling guidelines"

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ABBREVIATIONS

AI	Artificial Intelligence
AMA	Agency for Administrative Modernization (Portugal)
API	Application Programming Interface
BS	British Standards
CBHC	Cross-border Healthcare
CDA	Clinical Document Architecture
CE	Conformité Européenne (European Conformity)
CEN	European Committee for Standardization
cMHAFF	Consumer Mobile Health Application Functional Framework
CoLab	Collaborative Laboratories
DAQ	Digital Assessment Questionnaire (England)
DiGA	Digital Health Applications (Germany)
Digi-HTA	Digital Health Technology Assessment (Finland)
DiPA	Digital Nursing Applications (Germany)
DTAC	Digital Technology Assessment Criteria (England)
DTE	Digital Testing Environment
EDPS	European Data Protection Supervisor
EEHRxF	European electronic health record exchange format
EHDS	European Health Data Space Regulation
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
ENISA	European Union Agency for Network and Information Security
EU	European Union
EUDAMED	European Database on Medical Devices
EUnetHTA	European Network for Health Technology Assessment
FAQ	Frequently Asked Questions
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GPSD	General Product Safety Directive
GPSR	General Product Safety Regulation
HL7	Health Level 7
HTA	Health Technology Assessment
HTAR	Health Technology Assessment Regulation
ICD-10	International Classification of Diseases 10th Revision
ICHI	International Classification of Health Interventions
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise

ISO	International Organization for Standardization
IVDD	*In Vitro* Diagnostic Directive
IVDR	*In Vitro* Diagnostic Regulation
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
NICE	National Institute for Health and Care Excellence (England)
NIS	Network and Information Systems Directive
NIS2	Network and Information Systems Directive 2
PAM	Patient Administration Management
PAS	Publicly Available Specification
PECAN	Prise en Charge Anticipée Numérique (France)
PICO	Patient, Intervention, Comparator, Outcome
PII	Personally Identifiable Information
PLD	Product Liability Directive
SOP	Standard Operating Procedure
TR	Technical Report
TS	Technical Specification
UNI	Ente Nazionale Italiano di Unificazione (Italian National Unification Body)
URL	Uniform Resource Locator
WCAG	Web Content Accessibility Guidelines
WP8	Work Package 8

EXECUTIVE SUMMARY

In March 2025, the **European Health Data Space Regulation (EHDS)** entered into force, marking a pivotal step toward its phased implementation starting in March 2027. This regulation establishes rules for the use of health data to enhance healthcare delivery, research, innovation, and policymaking. A significant aspect of the EHDS is the establishment of common standards and compliance rules to ensure interoperability of data and digital solutions for healthcare across EU member states. This includes mandating that all electronic health record systems (EHR systems) align with the European electronic health record exchange format (EEHRxF), thereby facilitating seamless data exchange, and setting the rules for devices, such as wellness applications that want to share health data with EHR systems.

Xt-EHR is a Joint Action of notified EU/EEA Member State bodies that creates a common ground to shape the EHDS framework for primary use in Europe. It supports the European Commission's policy priority for 'A Europe fit for the digital age' and aims to provide the necessary documentation to leapfrog the adoption of common specifications in EHR systems across Europe based on the EEHRxF. The development of the specifications under the Xt-EHR Joint Action is firmly rooted in a multi-stakeholder approach. The deliverables reflect where applicable extensive consultation with national authorities, healthcare professionals, patient and consumer representatives, public health organisations, medical societies, industry experts, Standard Development Organisations, and other key actors. Their feedback to the first draft of D8.3 has been instrumental in shaping the priorities, technical specifications, and governance recommendations presented in this document.

WP8 (Work Package 8) of the Xt-EHR project is aiming to support the conformity schemes that are to be developed for the implementation of EHDS provisions. To achieve the overall objectives and tasks of WP8, a key focus is the development of guidelines to support the EHDS Regulation. The current deliverable *"D8.3 EHDS Guidelines for app manufacturers of wellness applications in Europe"*, includes structured guidelines for wellness application manufacturers to comply with the requirements deriving from the EHDS Regulation.

To arrive there, the main goals pursued by this deliverable, are the following:

- To evaluate the applicability of the CEN-ISO/TS 82304-2 quality requirements relating to interoperability and security in providing a basis for the labelling scheme for wellness applications [Article 47 to 49], (Chapter 4)
- To analyse the results of Label2Enable, in particular the handbook for CEN-ISO/TS 82304-2, and see its relevance based on the adopted regulation under EHDS to propose guidelines for wellness applications considering the EU regulations in place, to support the development of wellness applications according to interoperability and security requirements under ISO standards but also as a checklist of actions to be performed to operate in a secure and ethical way within the European Health Data Space. (Chapter 5)

Additionally, this deliverable describes the role of wellness applications in the EHDS (Chapter 2), introduces CEN-ISO/TS 82304-2 and Label2Enable, listing applicable legislations, standards and ongoing initiatives and the extent to which these informed CEN-ISO/TS 82304-2 and the Label2Enable handbook for CEN-ISO/TS 82304-2 (Chapter 3), and provides further guidance for next steps in the implementation based on the combined analysis of all of the above. (Chapter 6)

[To add a final paragraph after the second round of consultations highlighting key findings.]

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1. INTRODUCTION

The **European Health Data Space Regulation** (EHDS Regulation) is a significant regulatory initiative by the European Union aiming to enhance accessibility and utilization of health data across member states. Its core objectives are to improve individual access to electronic health data and to facilitate the sharing of such data for care provision as well as making such data accessible for secondary use for policy making, education, research and innovation. The EHDS aims to create a trusted environment for secure access and processing of a wide range of health data. It builds upon existing frameworks such as the General Data Protection Regulation (GDPR), the Data Governance Act, the Data Act, and the Network and Information Systems Directive, maintaining or enhancing rights under the existing legislation and providing specific sectoral rules tailored to supporting easier access to health data to support care, health improvement and research.

In particular, the aim of this Regulation is to establish the EHDS in order to improve natural persons' access to and control over their personal electronic health data in the context of healthcare, as well as to better achieve other purposes involving the use of electronic health data in the healthcare and care sectors that would benefit society, such as research, innovation, policy-making, public health, managing health threats through preparedness and proper response, including preventing and addressing future pandemics, patient safety, personalised medicine, official statistics or regulatory activities. In addition, this Regulation's goal is to improve the functioning of the internal market by laying down a uniform legal and technical framework, in specific for the development, marketing and use of electronic health record systems ('EHR systems') in conformity with Union values. The EHDS is a key element in the creation of a strong and resilient European Health Union.

The **EHDS** Regulation includes requirements for **wellness applications that intend to claim interoperability with EHR systems**. The data from such applications may serve an important role for continuous health monitoring and personalised care**.** Such data may effectively contribute to better health outcomes and better patient engagement. This is useful particularly if more complete information is needed which combines health and fitness data collected by the user, and official health records collected by health professionals. Additionally, re-using health data obtained from wellness applications for secondary use as set out by the EHDS Regulation, may also contribute to public health.

1.1 Purpose and scope of the deliverable

The main deliverable of Task 8.3 are the guidelines for wellness application manufacturers to support compliance with EHDS requirements, considering the EU regulations in place, to support the development of wellness applications according to interoperability and security requirements under ISO standards, but also as a checklist of actions to be performed to operate in a secure and ethical way within the European Health Data Space. (Chapter 5)

To arrive at these guidelines, we evaluated as per the assignment of Task 8.3 the results of Label2Enable, in particular the Label2Enable handbook for CEN-ISO/TS 82304-2, to see its relevance based on the adopted regulation under EHDS, in providing the basis for the mandatory labelling scheme for wellness applications. Interoperability and relevant requirements and provisions under EHDS Articles 47 to 49 and Annex II were considered as the basis of reference. (Chapter 4)

This evaluation is complemented by an introduction to wellness applications, their role in the EHDS, and a flowchart to assist manufacturers in deciding if their product is a wellness application, and, if so, which Articles apply (Chapter 2), as well as a short overview of CEN-ISO/TS 82304-2, the current legislative framework, standards, and existing initiatives and their uptake in the Label2Enable handbook. (Chapter 3)

It is important to note that according to the project description, Task 8.3 was to use the CEN-ISO/TS 82304-2 definition of apps that considers health and wellness apps as one.

> **'health and wellness app'** means app (software application that can be executed (run) on a computing platform) intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care"**.**
>
> CEN-ISO/TS 82304-2 definitions

However, for the purpose of this document we used the EHDS definition for wellness applications, which is *"any software, or any combination of hardware and software, intended by the manufacturer to be used by a natural person, for the processing of electronic health data, specifically for providing information on the health of natural persons, or the delivery of care for purposes other than the provision of healthcare"*. Note that CEN-ISO/TS 82304-2 did not intend to distinguish between care and healthcare, and that the ISO definition includes both wellness apps and medical devices, whereas the EHDS definition of wellness applications intends to exclude medical devices, see for more detail on this topic and definitions Chapter 2.

Based on the previous analysis and outcomes, Task 8.3 will propose guidelines for wellness applications in Europe as per EHDS Regulation provisions and in accordance with interoperability and security requirements under ISO standards. This will result in a set of guidelines for wellness app manufacturers to be compliant with the new regulation requirements. The EHDS and these guidelines apply to wellness applications for which interoperability with an EHR system is claimed regardless if the manufacturer of such application is based in the EU. Although the EHDS does not have a specific provision for wellness application manufacturers for outside of the EU, Regulation (EU) 2023/988 on general product safety (GPSR) requires manufacturers that are not based in the EU to establish an operator within the EU that is responsible for compliance with the GPSR, and they should be identified on the product. Their role includes being the point of contact for supervisory authorities and conducting compliance checks of the product's documentation and safety information. These requirements for representation in the EU are in line with products specific EU legislation such as MDR for medical devices, and EHDS Article 31(1) for EHR systems.

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2. INTRODUCTION TO WELLNESS APPLICATIONS AND THEIR ROLE WITHIN THE EHDS

2.1 Introduction to the role of wellness applications within the EHDS

The European Health Data Space Regulation (EHDS) is a significant regulatory initiative by the European Union aiming to establish a common framework for the use and exchange of electronic health data across the EU, including setting up the compliance requirements framework for manufacturers of wellness applications who wish to claim interoperability with electronic health record (EHR) systems to enable the users of such applications to insert their health data from the wellness application into their own EHR.

The core objectives of the EHDS are to empower individuals to access, control and share their electronic health data for the delivery of healthcare ('primary use of data') within and across the national borders of EU countries as well as to enable the reuse of a wide variety of health data for research, innovation, policy-making and regulatory activities ('secondary use of data'). It also aims to foster the single market for EHR systems [Article 1(1)(2)] as well as EHDS compliant products, which could be medical devices, *in vitro* diagnostic medical devices, high-risk artificial intelligence (AI) systems as well as wellness applications, so that in all Member States procurers and users of such products may benefit from enhanced availability of and access to high-quality EHDS compliant products for their specific needs [Recital 51].

The EHDS acknowledges that although wellness applications are to be used outside healthcare provision, data generated by them can be useful for healthcare purposes to a certain extent. The limitation can be explained as follows: while a wellness app is not to be used by a health professional as a tool in providing healthcare, a health professional could use data generated by the use of a wellness app and inserted in their own EHR by a patient in the context of providing healthcare to that patient [Recital 51]. Wellness applications may have a variety of uses e.g. supporting continuous wellness monitoring, personalising care to assist with daily living, as well as preventative approaches to physical and mental health.

Key aspects of compliance with the EHDS

While the EHDS lays down common rules for all EHR systems in relation to the two mandatory harmonised software components, namely the 'European interoperability software component' and the 'European logging software component', the requirements for wellness applications are limited to those that claim interoperability with an EHR system and only to the extent to which the wellness app manufacturer claims interoperability. This means the manufacturer chooses which data can be inserted under which range of circumstances into the EHR of the wellness app user [Article 1(2)(b)]. Accordingly, the EHDS compliance scheme distinguishes between the conformity assessment of EHR systems and wellness applications:

Table 1 Key difference between EHR systems and wellness applications

EHDS compliance scheme: key difference between EHR systems and wellness applications	
Mandatory certification for EHR systems	**Mandatory labelling for wellness applications**
All EHR systems must show a CE marking of conformity [Article 41]. Such conformity will be tested by the manufacturer using the European digital testing environment [Article 40]	Where the manufacturer of a wellness application claims interoperability with an EHR system, the wellness application must be accompanied by a label. This label will be issued by the manufacturer and indicates the categories of electronic health data for which compliance with the common specifications [Article 36] and essential requirements [Annex II] is confirmed [Article 47]

This distinction reflects on the fact that a large number of wellness applications are available, but the data produced by many of them have a limited relevance for healthcare purposes, making a certification scheme disproportionate [Recital 49].

In order to make electronic health data transmissible from wellness applications and receivable by EHR systems, the data needs to be interoperable with the European electronic health record exchange format (EEHRxF) [Article 15, Recital 26]. The EHDS identifies 'priority categories of personal electronic health data' [Article 14] - patient summaries, electronic prescriptions and dispensations, medical imaging studies and related imaging reports, medical test results and discharge reports - and links the majority of the obligations of manufacturers to these data categories. Of these categories, the patient summary is in particular applicable to wellness app manufacturers, as it contains a sub-category called "patient-provided data" [Annex I 1.15]. which includes any data a patient may wish to insert into their EHR, including data that originates from a wellness app [Article 5].

Upon meeting the requirements, the manufacturer is also required to issue a label, which clearly indicates its compliance with those specifications and requirements [Article 47(1)] and the categories of the data processed by the wellness application for which interoperability is claimed. The manufacturer will then need to register the wellness application in the EU database for wellness applications interoperable with EHR systems which will be established by the European Commission [Article 49]. Also, the manufacturer needs to inform its users about the effect of interoperability. See Figure 1 and more details in the next point.

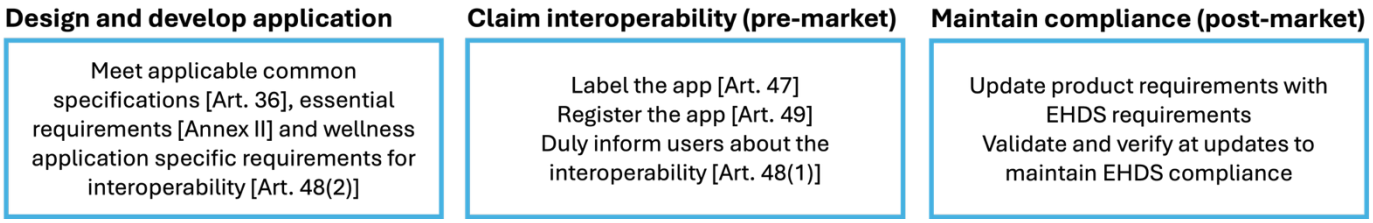

Figure 1 Product lifecycle compliance - Article 47 to 49

Meeting the requirements is the responsibility of the manufacturer. The guidelines below are designed to help manufacturers achieve compliance in order to allow them to issue the label and register the wellness app in order to market it to users. Where relevant, the guidelines refer to CEN-ISO/TS 82304-2 meaning that complying with the latter would imply a presumption of conformity with certain EHDS requirements and therefore both the manufacturer and the market surveillance authorities tasked to check compliance with essential requirements in Annex II can be reassured of meeting the relevant requirements.

Additionally, in order to ensure that the interoperability features of a wellness application work as intended, and also as a way of demonstrating compatibility with European interoperability software components of EHR systems, the manufacturer may use the European digital testing environment (DTE). DTEs will be operated across the EU by Member States for the assessment of the harmonised software components of the EHR systems. EHR systems must use the DTE and include its result in the technical documentation. Although not mandated by law, using the DTE on a voluntary basis offers manufacturers of wellness applications an opportunity to test their products and therefore gain the trust of customers to use their services with confidence.

Safeguarding personal electronic health data of users of wellness applications

The EHDS Regulation builds on GDPR and grants additional rights for access and portability of personal electronic health data, which creates a pool of rights that patients can exercise as depicted in Figure 2 below. Individuals have the right to insert information in their EHR which they can exercise through the "electronic health data access services" [Article 4(1)] or via EHDS compliant wellness applications [Article 48(2)]. Such data sharing from a wellness application is only possible based on consent given by the natural person concerned and may be exercised by the natural person or their proxy. The EHDS is clear that the manufacturer's claim regarding interoperability with EHR systems is limited exclusively to enable this data sharing [Article 48]. The consent mechanism needs to enable the user to choose which categories of health data from the wellness application are to be inserted in the EHR system and the circumstances of the data sharing [Article 48)2)], such as what data, how often, or based on what trigger to share.

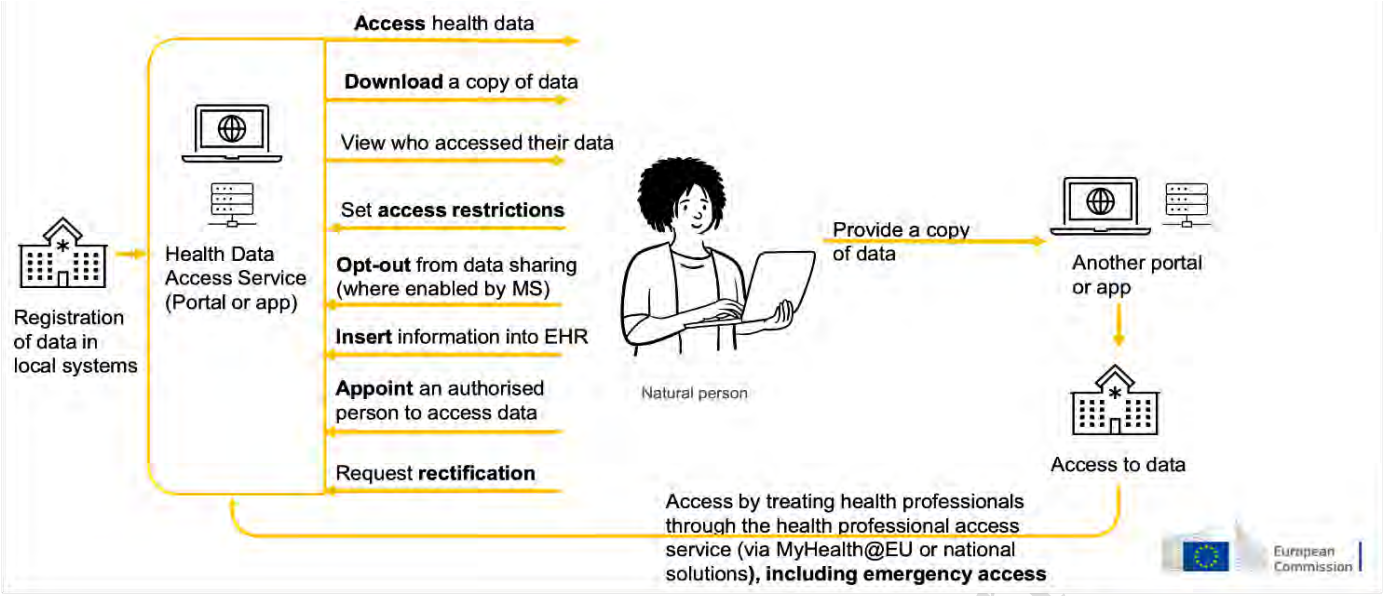

Figure 2 EHDS rights of natural persons in primary use

The EHDS Regulation requires that data added by natural persons in their EHR should be clearly distinguishable from data provided by health professionals or from medical devices [Article 5, Recital 12]. This mitigates any risk to patient safety that using data inserted via a wellness application may pose when a health professional takes into account patient-provided data. Although the requirement to make patient-provided data distinguishable rests with the EHR system, it is important for the manufacturers of wellness applications to understand the requirement given that they need to inform the users about the effects of their interoperability claims [Article 48(1), Recital 49].

The purpose of the wellness application labelling scheme is to support users in their choice of appropriate wellness applications with high standards of interoperability and security [Recital 49]. The labelling system also ensures that health professionals using EHR systems can trust that the data in question is inserted via an EHDS compliant wellness application as opposed to uploaded by the patient from an unknown source. The essential requirements set out that interoperability, safety and security features of products seeking compliance shall uphold the rights of natural persons [Annex II 1.3]. This should be understood within the context of the capacity of the wellness application to insert data into an EHR if the user provides valid consent.

Important to note that data protection and security requirements as per the General Data Protection Regulation (GDPR) continue to apply. The EHDS builds on and complements the GDPR. The two legal acts should be read together and therefore data sharing from the wellness app to an EHR system must comply with the three core components of security - confidentiality, integrity and authenticity – which could greatly contribute to fostering trust among the users.

Patients have the right to download their EHR data in EEHRxF through the health data access services and may choose to upload such data into a wellness application. Whilst the EHDS does not require a wellness app to process all data in accordance with the EEHRxF, if this is done voluntarily, the wellness app

manufacturer may provide functionality that uses data from the EHR provided by the patient to personalise or otherwise refine its services.

2.2 Is your product a wellness application subject to EHDS interoperability requirements?

> **'wellness application'** means any software, or any combination of hardware and software, intended by the manufacturer to be used by a natural person, for the processing of electronic health data, specifically for providing information on the health of natural persons, or the delivery of care for purposes other than the provision of healthcare.
>
> Article 2(2)(ab) of the EHDS Regulation

There are two main questions to address to establish if a product falls under the compliance scheme of the EHDS as a wellness application:

1. Does the product fall under the definition of a wellness application according to Article 2(2)(ab) of the EHDS Regulation; and if so,

2. Does the manufacturer of the wellness application want to claim interoperability with the harmonised components of an EHR system?

The flowchart in Figure 3 guides manufacturers of wellness applications in understanding if their products fall under the compliance scheme of the EHDS.

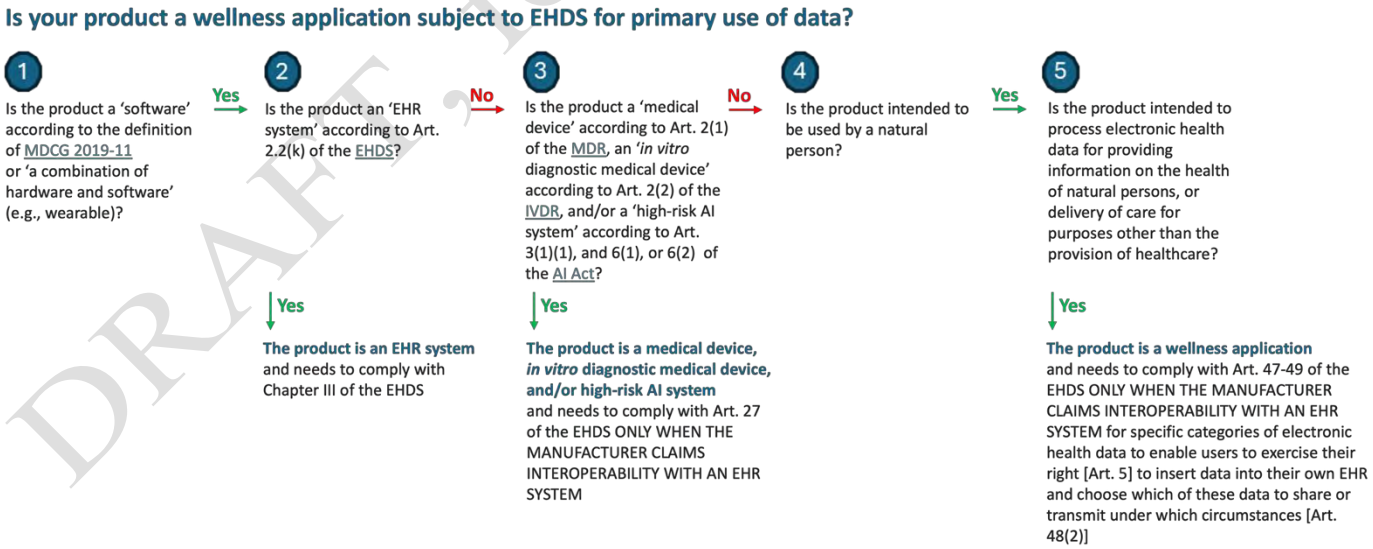

Figure 3 Flowchart is your product a wellness application?

The following details provide clarification of each step and give examples of wellness applications to address some frequently asked questions.

Note that the guidance is specific to compliance with interoperability requirements within the context of primary use of health data (healthcare provision). The availability of data from a wellness app for secondary use applies regardless of whether interoperability is claimed or not. If the wellness app manufacturer is a 'data holder' as defined in Article 2(2)(t), the manufacturer will have to make such data available for secondary use via the services of the Health Data Access Body. Given the broad scope of the types of data considered for secondary use, which include personal as well as non-personal data, most wellness application manufacturers will be required to make certain data they control available for secondary use.

1	**Is the product a software or a combination of hardware and software?**

A wellness application is software that users can use on hardware such as smartphones, tablets and desktop computers or a combination of hardware and software whereby the application is used together with a physical device, which might be a wearable, or embedded in a physical device a natural person uses. Given that the EHDS does not define software or hardware, we recommend using the definition set by MDCG 2019-11 which defines *"software" as a set of instructions that processes input data and creates output data*. For further information on the combination of software with hardware, please refer to MDCG 2023-4, which may be used as a baseline of understanding on the interaction between hardware and software for wellness applications as well. Alternatively, a tailored definition or resource could be developed or flagged, should such an accepted definition or resource already exist. However, it is important to note that the EHDS definition of wellness applications does not set any specific requisites, it simply says "software or any combination of hardware and software". Addressing feedback from the first round of consultation to add clarity if web apps are included, we propose to align with the response options for CEN-ISO/TS 82304-2 5.1.1.1 Which operating systems or platforms does the health app support? These options are Android-TM / iOS-R / Web app / Other (Multiple-choice).

2	**Is the product an EHR system?**

The EHDS definition of an EHR system is as follows:

> **'electronic health record system'** or **'EHR system'** means any system whereby the software, or a combination of the hardware and the software of that system, allows personal electronic health data

> that belong to the priority categories of personal electronic health data established under this Regulation to be stored, intermediated, exported, imported, converted, edited or viewed, and intended by the manufacturer to be used by healthcare providers when providing patient care or by patients when accessing their electronic health data;
>
> Article 2(2)(k) of the EHDS Regulation

As the EHDS has more detailed and stringent rules for EHR systems compared to wellness applications, and as they are mutually exclusive, it is important to establish whether a product in question is an EHR system or a wellness application. If the definition of EHR system applies, compliance requirements as set out in Chapter II, III and Annexes I-IV need to be followed to certify the product as an EHR system. For a product to be an EHR system:

- it has to process priority categories of data (patient summaries, electronic prescriptions and dispensations, medical imaging studies and related imaging reports, medical test results and discharge reports); whereby
- the processing performs *any* of the actions listed in the definition (allows the data to be stored, intermediated, exported, imported, converted, edited or viewed); AND
- it is intended to be used:
  - by healthcare providers when providing patient care, *or*
  - by patients when accessing their electronic health data.

See more about the definition in the FAQ of the Commission.[1] Although wellness applications enable their users to access certain kinds of electronic health data which they produce, they fall short on processing priority categories of data, which is one of the core elements of the EHR system definition. For example, if a mobile application is to be used as a patient portal to access data produced by healthcare services such as X-ray, blood tests results, it will be an EHR system. The purpose of wellness applications is to insert data about the health of a natural person or delivery of 'care' into the EHR, such as information about sleep, food intake, or exercise collected outside of the healthcare provision. See below in point 5 about what care means within this context.

Note that if the product is an EHR system, it may also be subject to the Medical Device Regulation and / or the AI Act, in which case the certification schemes created by those Regulations could also apply.

3	**Is the product a medical device, an *in vitro* diagnostic medical device, and / or a high-risk AI system?**

[1] https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en

The EHDS refers to the following definition of a medical device, *in vitro* diagnostic medical device and high-risk AI system as per the respective pieces of EU legislation Regulation (EU) 2017/745 on Medical Devices (MDR), Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices Regulation (IVDR) and Regulation (EU) 2024/1689 on Artificial Intelligence (AI Act):

> **'medical device'** means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
>
> - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
> - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
> - providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,
>
> and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
>
> The following products shall also be deemed to be medical devices:
>
> - devices for the control or support of conception,
> - products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.
>
> Article 2(1) of the MDR

> **'*in vitro* diagnostic medical device'** means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
>
> (a) concerning a physiological or pathological process or state,
> (b) concerning congenital physical or mental impairments,
> (c) concerning the predisposition to a medical condition or a disease,
> (d) to determine the safety and compatibility with potential recipients,
> (e) to predict treatment response or reactions,
> (f) to define or monitoring therapeutic measures.
>
> Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices.
>
> Article 2(2) of the IVDR

'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.

Article 3(1)(1) of the AI Act

1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

(a) The AI system is intended to be used as a safety component of a product, covered by the Union harmonisation legislation listed in Annex I,

(b) The product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall be considered to be high-risk.

Article 6(1) and (2) of the AI Act

Products that are not EHR systems themselves but want to insert data into the EHR of a user have to claim interoperability with the harmonised components of the EHR systems in order to do so.[2] According to Article 27 of the EHDS Regulation such products are:

- Medical devices or *in vitro* diagnostic medical devices [Article 2(1) of the MDR or Article 2(2) of the IVDR]
- Medical devices or *in vitro* diagnostic medical devices that are high-risk AI systems at the same time [Article 3(1)(1) and Article 6(1) of the AI Act]
- AI systems that are not medical devices or *in vitro* diagnostic medical devices themselves [Article 3(1)(1) and Article 6(2) of the AI Act]

Important to note that the key characteristic of medical devices is that these are *'intended by the manufacturer to be used for human beings for one or more specific medical purposes'* as listed in the MDR. Although there is a minor overlap between the definitions of medical devices and wellness applications (see below in Section 5), if a product is a medical device, it needs to follow the compliance regime set by EHDS in Article 27 and therefore is not addressed in this deliverable.

Based on the interplay between medical devices and high-risk AI systems as set out in Article 6 of the AI Act (Regulation 2024/1689), manufacturers need to establish if their product falls under both sets of requirements or just one of them. In short: most AI enabled high-risk medical devices, meaning class IIa, IIb, III, in which AI has significant influence on the product and / or its security features will be classified as high-risk AI systems as well. Although it is possible that an AI driven high-risk medical device, such as a fertility app used outside healthcare provision also meets the definition of a wellness application, it is very unlikely that an AI system which is not a medical device may intersect with the wellness applications given the nature of use cases set in Annex III of the AI Act. In any case, the same rules as stated above apply: compliance with EHDS as per Article 27, wellness application specific provisions as set out in Articles 47-49 are not applicable.

4	**Is the product intended to be used by a natural person?**

One of the distinctive features of a wellness application is that it is intended to be used by a natural person, such as a patient, a citizen or their representatives / proxies. Although health professionals are persons, just as patients, the key difference is whether they use a wellness application within their professional capacity. Wellness applications and their data are not meant to be used / accessed by health professionals as a matter of routine in healthcare provision. Data produced by a wellness application can be inserted into the EHR by or at the request of the application user, and health professionals may then access and use the data for the benefit of the patient if they so choose, but the data from the wellness application are additional information, rather than core information used to provide healthcare.

The intent of the manufacturer is of key importance. As seen in the definition of EHR systems, the intent there is to *"be used by healthcare providers when providing patient care or by patients when accessing their electronic health data".* Accordingly, an EHR system may be used by a natural person, but this use is only limited to accessing their electronic health data or exercising their right to data portability. These rights must be available to the patient with respect to at least the data in the priority categories but may be extended to other data if a Member State requires or the healthcare provider chooses to make other data available.

When it comes to medical devices, as defined in the MDR, *'intended by the manufacturer to be used for human beings for one or more specific medical purposes* [Article 2(1) MDR], these may include use by a health professional or by a natural person, such as some mental health apps that may be used independently by patients or by both of them simultaneously such as some remote monitoring systems. In contrast, a wellness application is defined in EHDS as intended to be used by a natural person for the processing of electronic health data, to provide information on the health of an individual or for care purposes other than healthcare.

5	**Is the product intended to process electronic health data for providing information on the health of natural persons, or delivery of care for purposes other than the provision of healthcare?**

This question has various components that should be analysed together as a whole to establish applicability. The intent of the co-legislators was to place wellness applications outside healthcare provision.

> **'healthcare'** means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;
>
> Article 3(a) of the Directive on the application of patients' rights in cross-border healthcare

Therefore, the definition should be read in a way that the condition "for purposes other than the provision of healthcare" relates not only to the products that process health data for providing information on the delivery of care but also to products that process health data for providing information on the health of natural persons.

Within the context of the wellness applications "care" is a very specific term that should be understood as professional service outside of healthcare. Given that the definition uses an "or" a product does not have to meet both criteria. Not all wellness applications have to be used in the care sector. Some may be used to care for the elderly or for those that have special needs to carry out essential activities of daily living, other wellness applications may only be used to provide information on the health of an individual, such as a fitness application.

> **'care'** means a professional service the purpose of which is to address the specific needs of a natural person who, on account of impairment or other physical or mental conditions, requires assistance, including preventive and supportive measures, to carry out essential activities of daily living in order to support his or her personal autonomy, persons, or the delivery of care for purposes other than the provision of healthcare.
>
> Article 2(2)(s) of the EHDS Regulation

Note that there are parts of the EHDS when it is clear that the intention of the co-legislators was to use the word '*care*' within the meaning of this definition, especially when 'healthcare and care sectors' are referenced but other instances are less obvious to interpret as such. Therefore, the context in which the

word care appears should be carefully analysed. For instance, 'care' in the definition of EHR system (Article 3(3)(k)) suggests the meaning of healthcare given that healthcare providers provide healthcare services to patients. The same logic applies to the phrase 'continuity of care' as in Recital 19. As explained above, the wording in the wellness application definition 'delivery of care' suggests meaning in the sense of Article 3(3)(s) as a professional service. But this does not rule out mobile applications that are used outside of the care sector as long as these are intended by the manufacturer to be used by a natural person for providing information on the health of natural persons for purposes other than the provision of healthcare.

Finally, to understand if a product is processing electronic health data, the definitions related to 'personal electronic health data' as per the EHDS [Article 2(2)(a-c)] as well as 'care' [Article 2(2)(s)] should be considered together with GDPR, for instance the definitions on 'personal data' and 'data concerning health'; [Article 4(1)(15)) GDPR].

Accordingly, health data when referred to in the context of wellness applications, means data about an identified or identifiable natural person related to the physical or mental health, including the provision of healthcare services, which reveal information about his or her health status. Important to note that health data may relate not just to physical or mental health of a person but also to services that can be traced back to the person in question. The same logic is applied to the wellness app definition, but the purpose of the care provided is limited: *"...processing of electronic health data, specifically for providing information on (1) the health of natural persons, or (2) the delivery of care for purposes other than the provision of healthcare*.

+	**Does the manufacturer claim interoperability with EHR systems to enable users to insert information from the wellness application into their EHR?**

EHDS requirements within the context of the primary use of data will only be applicable if the manufacturer claims interoperability. The interoperability requirements which concern the safety and security of the device will be limited to the extent to which users are enabled to share their data from the wellness application with an EHR system.

It means that the manufacturer decides which data categories to include in its EEHRxF interoperability feature and has to label the wellness application accordingly. The users of the wellness application can consider data sharing only within these parameters and decide whether to share any data at all, and if so, it can only be done based on consent. Setting the circumstances of such data sharing must be enabled, which may include data to send how often (i.e. once a week) or based on what trigger (i.e. if indicator X exceeds value Y).[2]

[2] https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en

Important to note that regardless of whether a manufacturer claims interoperability with EHR systems, or not, EHDS secondary use provisions may still apply. Also, there are further EU and Member State level legislative provisions such as GDPR, product liability [Directive 2024/2853] and cybersecurity laws [Regulation 2024/2853, Regulation 2019/881] and others such as the Radio Equipment Directive [RED 2014/53/EU] for wireless technologies that need to be taken into account when operating in the EU market.

2.3 Intended uses health and wellness apps according to CEN-ISO/TS 82304-2

Quality requirement 5.2.1.4 in CEN-ISO/TS 82304-2 reads: What is the intended use of the health app? Response options include System services, Inform, Simple monitoring, Communicate, Preventative behaviour change, Self-manage, Research, Treat, Active monitoring, Calculate, Diagnose, and Other. This overview is based on the NICE Evidence Standards Framework.[3] In consultation with NICE the intended use "Research" was added to the list in CEN-ISO/TS 82304-2, inspired by for instance the Zoe app that had nearly 5 million users during the COVID-19 pandemic.[4] CEN-ISO/TS 82304-2 does not make a distinction between health and wellness apps, nor between medical devices and those that are not medical devices, as this may differ per jurisdiction. The TS does include another quality requirement addressing the issue: 5.2.1.5 Are assessments done to establish whether the health app is a medical device and if applicable is regulatory approval obtained before the app is made available in each country?

System services
Health applications that improve health system efficiency. Unlikely to have direct and measurable individual health outcomes. Includes for example electronic prescribing systems, electronic health record platforms and ward management systems.

Inform
Health applications that provide information and resources to anyone or persons with, or at risk of, specific health issues[5]. Can include information on specific health issues or about healthy living. Includes for example applications describing a health issue and its treatment, applications providing advice for healthy lifestyles (such as recipes), and applications that signpost to other services.

Simple monitoring
Health applications that allow users to record health parameters to create health diaries. This information is not shared with or sent to others. Includes for example health tracking information such as from fitness wearables, symptom or mood diaries.

Communicate

[3] https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

[4] https://health-study.zoe.com

[5] "anyone" and "persons with, or at risk of, specific health issues" are response options to CEN-ISO/TS 82304-2 requirement 5.2.1.1 Who are the intended users of the health app?

Health applications that allow two-way communication between anyone or persons with, or at risk of, specific health issues and health professionals, informal carers[6], third-party organizations or peers. Health advice is provided by a health professional using the app, not by the app itself. Includes for example instant messaging applications for health and social care, video conference-style consultation software, and platforms for communication with informal carers or health professionals.

Preventative behaviour change

Health applications that are designed to change intended user behaviour related to, for example, smoking, eating, alcohol, sexual health, sleeping and exercise. Prescribed to intended users by a health professional. Includes for example smoking cessation applications, applications used as part of weight loss programs and applications marketed as aids to good sleep habits.

Self-manage

Health applications that aim to help persons with specific health issues to manage their health. Can include symptom tracking function that connects with a health professional. Includes for example applications that allow users to record, and optionally to send data to a health professional to improve management of their health issue.

Research

Health applications that generate data for research:

- measure the magnitude and distribution of a health problem.
- create understanding of the diverse causes or determinants of the problem.
- develop solutions or interventions that will help to prevent or mitigate the problem.
- implement or deliver solutions through policies and programs; and/or
- evaluate the impact of these solutions on the level and distribution of the problem.

Treat

Health applications that provide treatment for a specific health issue (such as CBT for anxiety), or guide treatment decisions. Includes for example applications for treating mental health or other conditions, and health professional-facing applications that advise on treatments in certain situations.

Active monitoring

Health applications that automatically record information and transmit the data to a health professional, informal carer or third-party organization, without any input from the user, to inform health management decisions. Includes for example applications linked to devices such as implants, sensors worn on the body or in the home. Data are automatically transmitted through the app for remote monitoring.

Calculate

Health applications that perform calculations that are likely to affect healthcare decisions. Includes for example applications for use by health professionals or users to calculate parameters pertaining to care, such as early warning system software.

Diagnose

[6] "anyone", "persons with, or at risk of, specific health issues", health professionals and informal carers are response options to CEN-ISO/TS 82304-2 requirement 5.2.1.1 Who are the intended users of the health app?

> Health applications that use data to diagnose a health issue in a person, or to guide a diagnostic decision made by a health professional. Includes for example applications that diagnose specified health issues using clinical data.
>
> Intended uses CEN-ISO/TS 82304-2

Of note, the intended uses or purposes of CEN-ISO/TS 82304-2 have been mapped in the Label2Enable handbook for CEN-ISO/TS 82304-2 with EU Medical Device Regulation (MDR). A health app intended by the manufacturer to be used, alone or in combination, for human beings for the MDR medical purposes:

- 'Prediction' and 'Prognosis' refer to the CEN-ISO/TS 82304-2 intended use 'Calculate', which may result in the separate CEN-ISO/TS 82304-2 intended uses 'Diagnose', 'Treat' and/or 'Self-manage' either in or outside the app.
- 'Alleviation of a disease, injury or disability', and 'Compensation for an injury or disability' refer to the CEN-ISO/TS 82304-2 intended use 'Self-manage'.

Other MDR related intended uses are phrased similarly: Diagnose/Diagnosis, Monitoring/Active Monitoring, Treatment/Treat, and if prevention for medical purposes: Prevention/Preventative behaviour change).

As such, the CEN-ISO/TS 82304-2 intended uses Self-manage, Treat, Active monitoring, Calculate and Diagnose, will generally refer to medical devices. The intended uses System services and Communicate will generally not refer to a wellness application, as in the case of System services the intended user is generally not the natural person, and in the case of Communicate a health professional is generally also an intended user. The intended use Inform will generally not process personal electronic health data (that is useful for healthcare purposes [Recital 49]). As a result, these apps also fall outside the scope of the EHDS definition for wellness applications. The remaining intended uses Simple monitoring, Preventative behaviour change, Research and to some extent Self-manage, are at present considered the most likely intended uses of wellness applications as defined by the EHDS. With regard to Preventative behaviour change, these types of apps may and may not be prescribed and may refer to primary, secondary, tertiary and quaternary prevention.[7] E.g., a recent meta-analysis showed 7.000 steps were correlated with significantly lower chances of several chronic health issues.[8] A Dutch citizen may as a result choose to use the app "Ommetje", an app initiated by the Dutch Brain Foundation (in Dutch: Hersenstichting) which intends to stimulate daily walks of at least 20 minutes, as 56% of the Dutch population does not engage enough in exercise. The app has 1.7 million downloads, recorded 272 million kms[9] and is not a medical device as it does not have a medical purpose.

To acquire a notion of the numbers of wellness applications vs medical devices, a study by the Dutch National Institute for Public Health and the Environment for the Dutch Ministry of Health Welfare and

[7] https://bjgp.org/content/69/678/28

[8] https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(25)00164-1/fulltext

[9] https://www.hersenstichting.nl/ommetje/

Sport, took a sample of 271 health apps. See Figure 4 for more detail on this sample and medical area of focus, which may provide a hint towards the potential usefulness [Recital 49] of data processed by these apps. In this sample, 1 in 5 was considered to qualify as a medical device under the MDR, at the time (2018) for more than half of these apps, it was not clear if they were CE-marked.[10]

Medical areas of the app	All apps	Only medical devices
Skin	36	6
Miscellaneous	35	1
Cardiac system	34	20
Mental health	28	4
Sleep	22	2
Pregnancy	21	2
Diabetes	19	5
Smoking	14	-
Lung diseases	11	-
Gastro-entomological diseases	10	1
Cancer	5	-
Chronic diseases	5	1
COPD	4	-
Dementia	4	2
Hearing	3	3
Balance management	2	1
Eyes	2	1
Liver	2	2
Neurology	2	1
(De)hydration	1	-
Allergies	1	-
Intravenous injections	1	1
Life style	1	-
Logopedics	1	-
Musculoskeletal system	1	-
Oral system	1	1
Pain management	1	1
Reanimation	1	-
Temperature	1	1
Thrombosis	1	-
Urinary system	1	-

Figure 4 Results from Dutch research into apps under the medical devices regulation

[10] https://www.rivm.nl/publicaties/apps-under-medical-devices-legislation-apps-onder-medische-hulpmiddelen-wetgeving

3. CEN-ISO/TS 82304-2

3.1 Evaluation of CEN-ISO/TS 82304-2 and its safety, security and interoperability requirements

CEN-ISO/TS 82304-2 was an assignment by the European Commission to the European Committee for Standardization (CEN). The initiative went global in its cooperation with the International Organization for Standardization (ISO). CEN-ISO/TS 82304-2:2021 Health software – Part 2: Health and wellness applications – Quality and reliability was published in July 2021. The core content of this Technical Specification (TS) is a health app quality assessment framework. The results are communicated in a score, a label inspired by the very effective EU Energy label, and a health app quality report. The label provides the results of the health app assessment in one glance. The health app quality report aims to provide the level of detail health professionals need to recommend a health app and give insurers a basis for decision-making on reimbursement.

According to the rationale of CEN-ISO/TS 82304-2:2021, the terms 'health app' and 'health and wellness app" are considered synonyms. The scope of health and wellness apps was part of the assignment, and as such decided upon by the European Commission. The term 'health app' has been used throughout the document for brevity, and to be consistent with the use of 'health software' in IEC 82304-1, rather than 'health and wellness software'. The document applies to all health and wellness apps, these include apps that qualify as medical devices and apps that do not. The quality characteristics for the 'Quality in use' model from ISO/IEC 25010:2011, 3.2, informed the development of CEN-ISO/TS 82304-2. These are: Effectiveness, Efficiency, Satisfaction and Risks Mitigation. A subset of the characteristics from the product quality model in ISO/IEC 25010, 3.3, were also considered. These are: Functional suitability, Usability and accessibility Interoperability, Reliability, Security, and Authenticity.

The assessment framework of CEN-ISO/TS 82304-2 consists of 81 questions (quality requirements). Sixty-seven of these questions are score-impacting quality requirement questions. A Delphi study with 83 experts from 8 stakeholder groups, 26 existing frameworks, subject matter expert guidance, an analysis of GDPR and MDR, and testing 11 Covid-19 symptom apps for the Dutch Ministry of Health Welfare and Sport, aside from regular ISO development processes, were foundational for this Technical Specification (TS)[1112], which intends to evolve to an International Standard (IS) in the upcoming revision.[13]

Section 4

Section 4 of CEN-ISO/TS 82304-2 explains the quality assessment process, and introduces the 4 quality aspects the 67 score-impacting quality requirements are grouped into, which were named after testing with persons with low health literacy:

[11] https://formative.jmir.org/2023/1/e43905

[12] https://www.iso.org/standard/78182.html

[13] https://www.iso.org/deliverables-all.html

- Healthy and safe (sub-aspects: Health requirements, Health risks, Ethics, Health benefit, Societal benefit)
- Easy to use (sub-aspects: Accessibility, Usability)
- Secure data (sub-aspects: Privacy, Security)
- Robust build (sub-aspects: Technical robustness, Interoperability)

Also, the purposes of the 81 quality requirements are introduced:

- Label content (question to capture information to be provided in the health app quality label)
- Requirement level (question to establish which subsequent questions apply)
- Colour coding (score-impacting requirements)
- Filtering (question to help app repository users search and filter for relevant apps)
- App assessment (question to enable app evaluation, response is provided to the app assessment organisation only)

Section 4 of CEN-ISO/TS 82304-2 also introduces the health app quality report, the set of answers to the quality requirement questions, excluding evidence provided to enable app assessment, that can be made available to potential customers and users of the health app to enable informed decision-making. (The Label2Enable project (2022-2024) co-designed with health professionals and medical societies this health app quality report, the detailed version of the CEN-ISO/TS 82304-2 label, with an intent to easily provide health professionals with the information they need to confidently recommend a health app. A separate article on this development is near ready for submission in Q3/4, 2025.

Section 5

Section 5 of CEN-ISO/TS 82304-2 includes the 81 quality requirements with their purpose, response options, evidence requirements, and explanatory notes.

Under sub-aspect 5.2.2 (Health risks) there is a wide range of quality requirements marking the safety elements and clarifying the safety controls that are implemented, focusing on health risks and their proportionality given the potential health benefits.

The ethical sub-aspect is elaborated under paragraph 5.2.3 (Ethics). In this part questions refer to ethical challenges and their assessment by intended users and health professionals, as well as independent ethics advisors and ethics advisory boards. The assessment of ethical challenges shall include measures to control the identified ethical challenges, testing and monitoring their effectiveness during development, deployment and use, and correcting measures deemed not effective. Ethical challenges include discrimination, stigmatization, fairness, bias in data sets, algorithms and users' interpretation, human agency, liberty, dignity and environmental wellbeing. Ethical issues covered in quality requirements beyond 5.2.3 are (adapted from Reference European Commission, High Level Expert group on artificial intelligence 2018, Ethics guidelines for trustworthy AI):

- technical robustness and safety
- privacy and data governance

- transparency (understand how the app achieves its decisions)
- individual and societal wellbeing
- accountability

Section 5.4 (Secure data) includes an extended set of questions that cover the assessment of health applications with regards to security elements. Major aspects covered in this part are the following:

- Privacy (Personally Identifiable Information- PII[14]) per se and in case of connection with devices or other sources, data minimization, retention policy of PII, privacy statement for the user (including different classifications based on different regulatory regimes). (As the GDPR uses personal data instead of PII, the Label2Enable handbook for CEN-ISO/TS 82304-2 refers to GDPR definitions, articles and principles relevant for wellness applications.)
- Assurance of the level of security controls and privacy protection through contractual agreements with controllers of PII, and opt-in and permissions for sharing PII with third parties
- Definition by the manufacturer of responsible persons for legal and regulatory compliance
- Security vulnerabilities management and incident-response procedures in place with all the elements of the relevant process
- Implementation of ISO 27001, established information security policy including an information security assessment,
- SOP (Standard Operating Procedure) for secure design, secure coding, security measures related to third-party libraries used in applications, unauthorised access prevention, secure sessions through authentication, authorisation and session management
- Security through organizational measures
- Encryption
- Security testing

Section 5.5.2 (Interoperability) outlines only basic aspects of interoperability:

- Accessibility of information on specifications, implementation guides of Application Programming Interfaces (APIs), terminologies
- Validation of data transferred via APIs
- Health related PII extracted by other platforms

Annexes of CEN-ISO/TS 82304-2

Annex A specifies the health app quality label design.

Annex B explains the health app quality score calculation method.

Annex C describes the rationale of the TS, in particular for its scope 'health and wellness apps'.

Annex D refers to product safety and lifecycle process recommendations.

Annex E provides information on application profile and contact tracing applications.

[14] Any information that (a) can be used to establish a link between the information and the natural person to whom such information relates, or (b) is or can be directly or indirectly linked to a natural person

Annex F refers to ethical considerations, acknowledging clearly that retaining and exchanging health data through applications may be both beneficial and impose threats for individuals' personal information. The areas covered by the quality and reliability criteria set out in this document, with an indication of the relevant sections in this document, are presented in relation to the Fundamental Rights Impact Assessment (FRIA).

3.2 Evaluation of the Label2Enable handbook for CEN-ISO/TS 82304-2

Label2Enable was a Horizon Europe project (2022-2024) that assessed and developed products and services to support multi-stakeholder needs in implementing of CEN-ISO/TS 82304-2. One of the main deliverables that is moreover considered of interest for Xt-EHR's aims to achieve manufacturer guidelines was the Label2Enable handbook for CEN-ISO/TS 82304-2 assessments (D2.2), the Annex to its Certification scheme (D2.4), which was built on:

- Testing the evolving handbook by assessing 24 applications with 5 app assessment organisations (Task 3.1)[15]
- Alignment with EU level legislation, EU values (Task 2.2) and EU and international standards
- A comparative analysis with European HTA frameworks, i.e. EUnetHTA core model, the Dutch Leidraad, English DTAC, Finnish Digi-HTA, French PECAN, the German DiGA, and the Australian assessment framework which is based on CEN-ISO/TS 82304-2
- Guidance for the health app quality report from the Label2Enable Healthcare professional advisory board which aims to support healthcare professionals in their decision-making on recommending health apps (Task 5.1)
- Advice from subject matter experts
- Scientific literature (especially for requirements which lacked EU level legislation and standardization, such as what is an age / gender / culturally appropriate app or what is adequate co-creation of an app with users)

The handbook specifies for each CEN-ISO/TS 82304-2 quality requirement:

- Additional evidence and guidance (to enable an adequate assessment)
- Sub-questions (the actual assessment)
- Pass / fail (what is sufficient evidence)
- Potential for automated assessment (in part or full, to further explore)
- Likely mandatory within the EU (which requirements are deemed mandatory to qualify for a label in the EU regulatory landscape, input from Task 2.2).

The methodology employed is displayed in Figure 5.

[15] https://formative.jmir.org/2025/1/e64565

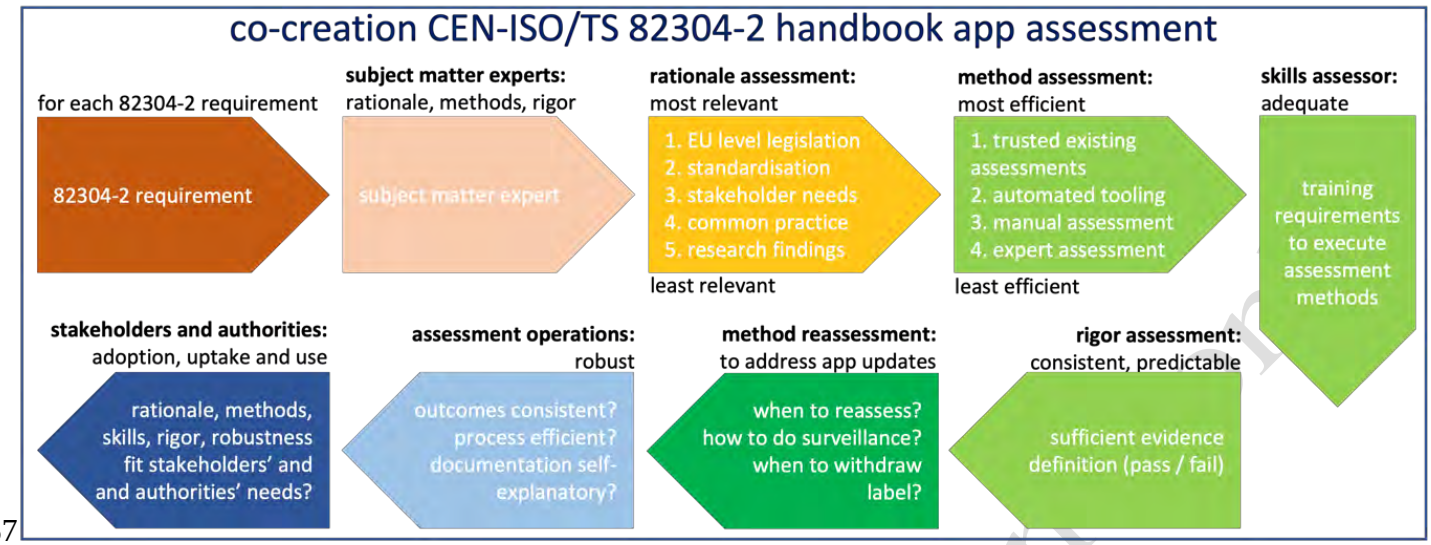

Figure 5 Co-creation CEN-ISO/TS 82304-2 handbook app assessment

The scoring mechanism for the labelling program for health apps as it is applied in the Label2Enable handbook, is the normative annex B of CEN-ISO/TS 82304-2:

- each of the 67 score-impacting quality requirements has a weight of either 1, 2 or 3 points
- A = 90+% of the weighted score, B = 80+% etc.

The 67 score-impacting CEN-ISO/TS 82304-2 quality requirements are phrased as yes / no / not applicable questions. Label2Enable co-created the handbook app assessment for CEN-ISO/TS 82304-2 and created for each of the 81 CEN-ISO/TS 82304-2 quality requirements sub-questions and what was called pass / fails:

- the pass / fail equation specifies which sub-questions need to be answered yes to get an overall yes for that specific score-impacting requirement
- a yes means the allocated points (weight 1, 2 or 3) are granted, a no means no points are granted

Currently, Label2Enable suggests a phased implementation with a pass / fail 2025 working towards the full pass / fail in 2027 to make sure manufacturers have some time to adjust their applications and make sure to see the difference in app quality as of 2025 (as opposed to mostly D/E scores).

The 82304-2 assessment framework refers to 28 standards, in part ISO standards, which is considerably more than any other framework in a list of 20 frameworks that the WHO assessed for the EU in 2018.[16] The handbook added, where applicable, further details from European and international standards in the "additional guidance and evidence" section. This section seems to have a similar purpose as the set of guidelines for app manufacturers to be compliant in the Task 8.3 deliverable.

[16] https://formative.jmir.org/2023/1/e43905

The handbook was built on third-party assessment, given clear indications in personal conversations with stakeholders (confirmed by the literature) that they need “more than the blue eyes of the app manufacturers”. Possibilities of automated testing and trusted existing assessments were explored indicatively in the handbook. This approach might deliver trust in a self-assessment (for interoperability and security).

The work on the health app quality report (D5.2, article to be submitted Q3/4 2025, see Figure 6) and label understandability (D4.2, D4.3, in total 3 articles, to be submitted Q3/4, 2025) and label effects on willingness to recommend apps (D5.1, 2 articles, 1 published, 1 in peer review) and willingness to download apps / display of the label (D5.3, article to be submitted Q3/4, 2025) may be interesting, given Article 47(3,9), and Recital 49: “providing transparency […] regarding compliance with requirements under this regulation, thereby supporting users in their choice of appropriate wellness applications with high standards of interoperability and security” and article 49 (publicly available EU database for registration of EHR systems, wellness applications, as well as medical devices, *in vitro* diagnostic medical devices and high-risk AI systems).

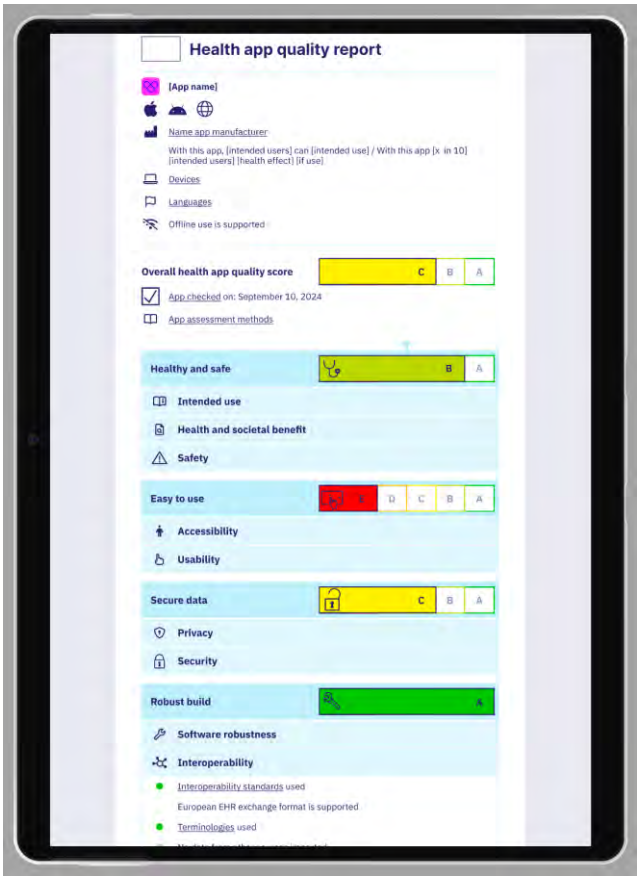

Figure 6 FIGMA visualization of the health app quality report, in which the sub-category Interoperability has been clicked, showing “European EHR exchange format is supported” (Label2Enable D5.2)

3.3 Considering the EU legislation in place

Building on Label2Enable deliverable D2.3, which provides an overview of EU level laws and values relevant for health apps, including mobile apps that are medical devices as well as wellness applications applicable in 2024, this section summarises the EU regulatory landscape in place as of July 2025 focusing on wellness applications only within the sense of the EHDS definition in Article 2(2)(ab). The EU Regulations most relevant to the provision and use of wellness applications are:

- General Data Protection Regulation (**GDPR**),
- European Health Data Space Regulation (**EHDS**).

GDPR is the primary law for data protection and privacy in the European Union. It applies to all organizations that process personal data of EU citizens, including wellness application manufacturers. Wellness applications must ensure compliance with GDPR when processing personal data, as well as personal health data (which is classified as "special category" data under the Regulation). The EHDS complements GDPR by facilitating data sharing in a secure and privacy-respecting manner, ensuring wellness applications can handle personal and health data while respecting user privacy rights. Key requirements related to the rights of natural persons enshrined in GDPR and further complemented by EHDS that manufacturers need to comply with include consent management, data protection by design, rights to data access and portability, and secure processing of personal health data.

Historical context

Label2Enable D2.3 includes a timeline about how the most relevant current EU secondary laws such as Regulations and Directives affecting health apps came into existence based on the Treaty on European Union (TEU), and the Treaty on the Functioning of the European Union (TFEU). The historical context intends to support a better understanding of the legislators' aims covering safe use of physical products, and then moving onto safe use of software, data protection and cybersecurity, and finally, fostering use of health data within the context of EHDS.

Safe use of physical products

The timeline starts with a focus on **safe use of physical products**. The Product Liability Directive (**PLD**), introduced in 1985, the Medical Device Directive (**MDD**) in line with the *In Vitro* Diagnostic Directive (**IVDD**), were revised in the following decade. In 2001, the General Product Safety Directive (**GPSD**) introduced a safety net covering products, aspects and risks not addressed by harmonisation legislation. The **Directive 2001/83/EC** on the Community code relating to medicinal products for human use[17] was flagged for health apps that are linked to the prescription or use of medicines. The PLD, GPSD, MDD/IVDD have in the meantime been replaced, Directive 2001/83/EC is currently under review as part of the Pharmaceutical package. While the PLD and GPSD (now GPSR) are relevant for wellness applications as detailed below, the other two pieces of law are not applicable given that wellness applications are not subject to MDD/MDR and are generally not linked to the prescription of medicines.

[17] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20250101

Safe use of software

The second step on the timeline is a focus on the **safe use of software**. A revision of the PLD resulted in the new Directive on liability for defective products (**new PLD**)[18], which was adopted in 2024 and extends the product definition to include software. The scope includes both medical devices and wellness applications, regardless of if they have a physical wearable component. The purpose of the legislation is to ensure that victims can claim compensation from manufacturers when they suffer damage caused by a defective product. A product is to be considered defective where the product does not provide the safety that a person is entitled to expect from it, or what is required under law. It is important to note that for example, it considers the lack of software updates under the manufacturer's control as well as the failure to address cybersecurity vulnerabilities as product defectiveness. Similarly, the General Product Safety Regulation (**GPSR**)[19], now covers products that are tangible, non-tangible or of mixed nature, including apps and software products. To meet the general safety requirement, the product must undergo a risk assessment, which evaluates its potential risks to consumer health and safety and takes into account all relevant aspects of the product. All potential risks should be eliminated or, if not possible, mitigated. Whenever possible, using the relevant European safety standards cited in the Official Journal of the EU is one way of ensuring your product can be considered safe. If no such standards exist, a product is considered safe if it meets the national health and safety requirements of the country where it is made available.[20] The GPSR compliments the requirements for online marketplaces by the Digital Services Act (**DSA**) which has been in force since February 2024. The DSA regulates online intermediaries and platforms such as marketplaces, content-sharing platforms, and app stores. Its main goal is to prevent illegal and harmful activities online and the spread of disinformation. The recently published MDCG 2025-4 - Guidance on the safe making available of medical device software (MDSW) apps on online platforms – provides clarification on obligations under the MDR/IVDR and DSA, however there are implications for health apps with no intended medical purpose such as wellness applications. The Guidance recommends clear product categories on app platforms: Medical Device (versus Health, Lifestyle, Medical) but it does not use the term 'wellness application'. To overcome the challenges of fragmented national HTA schemes, the EU Directive on Patients' rights in Cross-border Healthcare (**CBHC Directive**)[21] introduced a voluntary collaboration in 2013 which has been transformed recently by Regulation (EU) 2021/2282 on health technology assessment (**HTAR**)[22] to create an EU framework for the assessment of health technologies, including software applications. As EU level clinical assessments and related activities only relate to certain high-risk medical devices, wellness applications fall out of scope. However, the HTAR provides the framework for Member countries to enhance their cooperation on areas where they see the added value, which could lead to opportunities for CEN-ISO/TS 82304-2 to be incorporated into HTA assessment in the future for health

[18] https://eur-lex.europa.eu/eli/dir/2024/2853/oj/eng

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32023R0988

[20] https://ec.europa.eu/safety-gate/#/screen/pages/productSafetyLegislation

[21] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0024-20250112

[22] https://eur-lex.europa.eu/eli/reg/2021/2282/oj/eng

apps, which relates to the freedom of Member States to regulate other aspects of the use of wellness applications as flagged in Recital 50, while addressing the current fragmentation, flagged in Recital 7.

Data protection and cybersecurity

The third step in the timeline concerns **data protection and cybersecurity**. Regulation on (EU) 2016/679 protection of natural persons with regard to the processing of personal data and on the free movement of such data (**GDPR**)[23], was adopted in 2016. Given that many health apps, including wellness applications, process health data which may relate to someone's physical or mental health, or to the delivery of care revealing information about his or her health status, they must be compliant with GDPR for collecting, processing and giving access to or sharing such data. The **ePrivacy Directive** (2002/58/EC)[24] commonly known as "cookie law," focuses on privacy and the protection of personal data in electronic communications. It complements the GDPR in providing privacy protection across digital services. Given that wellness applications collect user data through digital means, manufacturers must ensure that their applications are compliant, especially concerning cookies, tracking technologies, and user consent for data collection. Purposes such as marketing, and unsolicited communications always require prior consent, however cookies strictly necessary for the functioning of the website or mobile app such as for authentication, and security are exempt. Directive (EU) 2016/1148 (**NIS Directive**) was adopted in 2016 to address the need for a high level of cybersecurity across the EU. This Directive was repealed by the **NIS2 Directive** (EU) 2022/2555[25], giving Member States until October 2024 to transpose the NIS2 into their national legislation, however some countries are lagging behind with implementation. NIS2 imposes requirements on medical device manufacturers and healthcare providers who may integrate networked devices. NIS2 is considered not applicable to wellness applications, unless a Member State designates certain manufacturers of wellness applications as "essential or important entities" due to their affiliation with healthcare providers, which is unlikely. The European Cybersecurity Certification was introduced by Regulation (EU) 2019/881 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification (**Cybersecurity Act**)[26] as a voluntary scheme, which countries may make mandatory under certain circumstances. This means harmonised safety requirements for app manufacturers whose product is intended to be provided within healthcare settings across the EU. This too by definition excludes wellness applications. Relevant to wellness applications, the above-mentioned rules are now complemented by Regulation (EU) 2024/2847 (**Cyber Resilience Act**)[27], which introduces standards to protect all digital products in the EU from cyber threats. The regulation applies to all products connected directly or indirectly to another device or network except for specified exclusions such as certain open-source software or services products that are already covered by existing rules, such as medical devices. The products within the scope of the legislation must comply with the essential cybersecurity requirements such as secure design, development, production, and vulnerability

[23] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0679-20160504
[24] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0058-20091219
[25] https://eur-lex.europa.eu/eli/dir/2022/2555
[26] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R0881-20250204
[27] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02024R2847-20241120

handling processes. The Act also mandates that manufacturers ensure these products are free from known exploitable vulnerabilities, provide security updates, and protect data confidentiality and integrity. Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (**AI Act**)[28], adopted in June 2024, may be relevant to some health apps, including wellness applications if they use AI technologies. Although the AI Act addresses concerns with regard to safety, security and fundamental rights in connection with AI systems and sets a wide range of requirements in line with the risk a product poses, given the limited risk profile of wellness applications, the rules that are likely to apply to wellness application manufacturers focus on transparency towards the users of their applications and AI literacy of their staff.

Fostering use of health data

The fourth and final step on the timeline focuses on **fostering use of health data** and includes the **EHDS**, Regulation (EU) 2022/868 on European data governance (**Data Governance Act**)[29], and Regulation (EU) 2023/2854 on harmonised rules on fair access to and use of data (**Data Act**)[30]. Although the Data Governance Act and the Data Act are essential to create a trusted framework for data use in which the EHDS can flourish, they do not create directly applicable obligations for wellness application manufacturers within the context of primary use, which is the scope of this deliverable. With respect to cross-border healthcare, the EHDS builds on the **CBHC Directive** that created the European Reference Networks for Rare Diseases (ERNs) as well as the eHealth Digital Service Infrastructure (**eHDSI**) used by Member States on a voluntary basis to exchange the first types of priority categories of personal health data for primary use: ePrescriptions/ eDispensations and patient summaries. Within the framework of EHDS, the MyHealth@EU infrastructure replaces the eHDSI (and related provision of the CBHC Directive) and will become mandatory for all Member States. It is relevant for the wellness applications to the extent of data inserted into an EHR by using the EEHRxF via the user's patient summary, given that the patient summary can be exchanged across borders.

3.4 Development of wellness applications under ISO standards

Article 36 of the EHDS specifies that the Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements laid down in Annex II and that where relevant these specifications shall take into account the state-of-the-art standards for health informatics. CEN-ISO/TS 82304-2 built on IEC 82304-1:2016, *Health software — Part 1: General requirements for product safety*, IEC 62304:2006, *Medical device software — Software life cycle processes,* BS PAS 277:2015, *Health and wellness apps. Quality criteria across the life cycle. Code of practice,* HL7, *Consumer Mobile Health Application Functional Framework (cMHAFF)*, Release 1, and UNI/TR 11708, *Health Informatics - Criteria to*

[28] https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng
[29] https://eur-lex.europa.eu/eli/reg/2022/868/oj/eng
[30] https://eur-lex.europa.eu/eli/reg/2023/2854/oj/eng

identify APPs in the wellness, social and health context , and referenced on top within the assessment framework of CEN-ISO/TS 82304-2 (excluding the definition section) to support manufacturers:

ISO 639-3, *Codes for the representation of names of languages — Part 3: Alpha-3 code for comprehensive coverage of languages*

ISO 9241-210:2019, *Ergonomics of human-system interaction — Part 210: Human-centred design for interactive systems*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO/TR 16982:2002, *Ergonomics of human-system interaction — Usability methods supporting human-centred design*

ISO/IEC 27001:2013, *Information technology — Security techniques — Information security management systems — Requirements*

ISO/IEC 27701:2019, *Security techniques — Extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management — Requirements and guidelines*

ISO/IEC 29184, *Information technology — Online privacy notices and consent*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEEE, IEEE standard computer dictionary: a compilation of IEEE standard computer glossaries. New York: Institute of Electrical and Electronics Engineers; 1990

AICPA, *SOC 2® - SOC for Service Organizations: Trust Services Criteria* [viewed 2020-09-07].[31]

ANT+. *What is ANT+* [viewed 2020-09-07].[32]

Australian Signals Directorate, 2020. Australian Government Information Security Manual (ISM), [viewed 2020-09-07]. https://www.cyber.gov.au/acsc/view-all-content/ism

CREST, 2020. Assurance in Information Security [viewed 2020-09-07].[33]

ENISA, 2019. Smartphone Guidelines Tool [viewed 2020-09-13].[34]

European Commission, European Innovation Partnership on Active and Healthy Ageing, 2020. Blueprint [viewed 2020-09-13].[35]

European Commission, High Level Expert Group on Artificial Intelligence, 2018. Ethics guidelines for trustworthy AI, [viewed 2020-09-07].[36]

Health Information Trust Alliance (HITRUST), *HITRUST Common Security Framework.*[37]

National Institute for Health and Care Excellence (NICE), 2019. *Evidence standards framework for digital health technologies.*[38]

[31] https://www.aicpa.org/interestareas/frc/assuranceadvisoryservices/aicpasoc2report.html

[32] https://www.thisisant.com/consumer/ant-101/what-is-ant

[33] https://www.crest-approved.org/

[34] https://www.enisa.europa.eu/topics/iot-and-smart-infrastructures/smartphone-guidelines-tool

[35] https://ec.europa.eu/eip/ageing/blueprint_en

[36] https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai

[37] https://hitrustalliance.net/hitrust-csf/

[38] https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf

OWASP, *OWASP Mobile Security Testing Guide.*[39]
OWASP, *OWASP Secure Coding Practices-Quick Reference Guide*.[40]
OWASP, 2020. *OWASP Top Ten.*[41]
Personal Connected Health Alliance, *Personal connected health*.[42]
UNICEF, *Communicating with children (Guideline 1A)*.[43]
W3C, 2018. *Web Content Accessibility Guidelines (WCAG) 2.1*.[44]
WHO, 2016. *Monitoring and evaluating digital health interventions: A practical guide to conducting research and assessment.*[45]
WHO, 2018. *Classification of digital health interventions v1.0 (WHO/RHR/19.06)*.[46]
WHO, 2020. *Research – Overview.*[47]
Xcertia, 2019. *mHealth App Guidelines.*[48]
ISO/IEC 27017, *Information technology — Security techniques — Code of practice for information security controls based on ISO/IEC 27002 for cloud services*
ISO/IEC 27018, *Information technology — Security techniques — Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors*
ISO 13131, *Health informatics — Telehealth services — Quality planning guidelines*
IEC 62304:2006/AMD1:2015, *Medical device software — Software life cycle processes — Amendment 1*
IEC 62366-1:2015/AMD1:2020, *Medical device software — Software life cycle processes — Amendment 1*

Label2Enable created an ISO 17000 compliant certification scheme. The Label2Enable handbook for CEN-ISO/TS 82304-2 employs recognized standards such as ICD-10 (diseases and related health problems), which was also adopted by the German DiGA, ICHI (health interventions), and PICO (Patient, Intervention, Comparator, Outcome) to support health professionals in their decision-making, provides several references to resources that may support manufacturers in developing quality health apps and complying with EU level legislations (referring to MDR, GDPR, EHDS, Directive 2001/83/EC on the Community code relating to medicinal products for human use, the NIS2 Directive, and Cyber Resilience Act). These resources include EUDAMED, several MDCG documents, EDPS guidance, a first reference to the EEHRxF, several additional ISO and IEC standards, IEEE 5Rights Principles for Children (age-appropriate digital services), several articles ranging from the ethical dialogue, the behaviour change wheel, (inclusive) usability testing, behavioural design thinking, to co-creation, tooling such as Flesch-Kincaid (understandability), readable.com, inclusive language guides, and several resources to support (cyber)

[39] https://owasp.org/www-project-mobile-security-testing-guide/
[40] https://owasp.org/www-project-secure-coding-practices-quick-reference-guide/migrated_content
[41] https://owasp.org/www-project-top-ten/
[42] https://www.pchalliance.org/
[43] https://www.unicef.org/cwc/cwc_58605.html
[44] https://www.w3.org/TR/2018/REC-WCAG21-20180605/
[45] https://www.who.int/reproductivehealth/publications/mhealth/digital-health-interventions/en/
[46] https://www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/
[47] https://www.who.int/health-topics/research/
[48] https://www.himss.org/sites/hde/files/media/file/2020/04/17/xcertia-guidelines-2019-final.pdf

security, as well as an initial analysis of the potential for automated assessment tooling, both from standardisation organisations and commercial entities.

3.5 Evaluation of ongoing initiatives

Recital 7 of the EHDS refers to several Member States who have taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data to the central EHR system, for instance by a system of certification, detailing that not all Member States have put in place such systems and those Member States that have implemented them have done so in a fragmented manner. Recital 50 states that Member States should remain free to regulate other aspects on the use of wellness applications, provided that the corresponding rules are in compliance with Union law.

The Member State responses to the survey (**Annex I**) we conducted in May 2024 to identify wellness application labelling practices, include some of these Member State initiatives, which mostly concern medical device apps and not wellness applications. Most ongoing initiatives stem from a variety of national and international health technology assessment (HTA) frameworks and focus on medical devices, others are not (or not yet) related to HTA:

- The EUnetHTA Core Model
- The Dutch Leidraad 1055
- Digi-HTA in Finland
- France's PECAN framework
- Germany's DiGA pathway
- Catalonia (Spain)'s TIC Salut Social Foundation certification
- England's Digital Technology Assessment Criteria (DTAC)

Comparative analyses with all of the above frameworks, and the Australian assessment framework which is based on CEN-ISO/TS 82304-2, informed the Label2Enable handbook for CEN-ISO/TS 82304-2. Harmonisation would offer manufacturers a strong foundation for scalability of digital health solutions within the EU and beyond and positively affect an affordable supply of quality health apps being available across Europe in the many official EU languages.

An interest in harmonisation, a common framework and learning from previous initiatives is apparent from a growing number of:

- comparative analyses (for CEN-ISO/TS 82304-2: Catalonia[49], Finland[50]),
- pilots (for CEN-ISO/TS 82304-2 or a subset thereof: The Netherlands, Norway, Sweden),

[49] https://mhealth.jmir.org/2025/1/e67858

[50] https://oys.fi/fincchta/wp-content/uploads/sites/21/2023/02/comparison-report-of-digi-hta-and-cen-iso-ts-82304-2-2021.pdf

- frameworks building existing initiatives (for CEN-ISO/TS 82304-2 currently: Catalonia (Spain)[51], Australia[52], and Italy for telehealth which includes health apps[53]),
- projects like the Digital Medical Devices project (although as apparent from the name focused on medical devices)[54], and
- several articles and reports[555657585960], which generally highlight Germany[61], Belgium[62], France[63] and England (previously DAQ[64], now DTAC, yet currently under review[65]) as frontrunners. Research and learnings from these initiatives are highly recommended to inform implementation strategies.

Norway's "Safer Health Applications" initiative (Oct 2021 to Nov 2022) led by the Directorate of Health and carried out in collaboration with the Norwegian Health Network and the Directorate for eHealth, is the clearest example of a pilot for wellness applications. The initiative aimed at facilitating better quality assurance of applications within the Norwegian healthcare system and used a subset of CEN-ISO/TS 82304-2 requirements complemented with requirements used by the Norwegian Health Network to make health applications available on the national platform "Helsenorge", as well as requirements specific to Norwegian conditions. The assessment method was self-declaration (at the time the Label2Enable handbook was not yet available). The Norwegian Directorate of Health has recently published a recommendation for quality assurance of health and wellness applications based on CEN-ISO/TS 82304-2.[66]

France provides a list of assessed applications in Mon Espace Santé: "Des solutions utiles pour votre santé: Des services dans le domaine de la santé, du bien-être ou du maintien de l'autonomie pour mieux gérer votre santé."[67]

[51] https://mhealth.jmir.org/2025/1/e67858

[52] https://www.digitalhealth.gov.au/about-us/strategies-and-plans/assessment-framework-for-mhealth-apps

[53] https://formative.jmir.org/2025/1/e67855

[54] https://eithealth.eu/external-collaborations/european-taskforce-for-harmonised-evaluations-of-digital-medical-devices-dmds/, https://www.nature.com/articles/s41746-025-01697-w

[55] https://www.nature.com/articles/s41746-022-00573-1

[56] https://www.nature.com/articles/s41746-024-01263-w

[57] https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5e1496716&appId=PPGMS

[58] https://www.who.int/europe/publications/m/item/digital-health-in-the-who-european-region-the-ongoing-journey-to-commitment-and-transformation

[59] https://www.has-sante.fr/upload/docs/application/pdf/2021-09/assessment_of_apps_in_the_mobile_health_mhealth_sector._overview_and_quality_criteria_of_medical_content.pdf

[60] https://kce.fgov.be/sites/default/files/2023-01/KCE_362_Evaluation_Digital_Medical_Technologies_Report.pdf

[61] https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html

[62] https://mhealthbelgium.be/apps

[63] https://gnius.esante.gouv.fr/fr/financements/fiches-remboursement/prise-en-charge-anticipee-numerique-pecan

[64] https://digital.nhs.uk/services/nhs-apps-library

[65] https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

[66] Apper for helse og velvære - Kvalitet og pålitelighet (SN-CEN ISO/TS 82304-2:2021) - Helsedirektoratet

[67] https://www.monespacesante.fr/

Germany is the undisputed frontrunner for medical devices and research surrounding implementation of an assessment framework. At the time of writing (July 28, 2025) there are 57 reimbursed health apps (DiGA), these have undergone an assessment by the BfArM. A more recent addition are Digital Nursing Applications (DiPA)[68]. Even though DiPA are not necessarily medical device applications the requirements for DiGA and DiPA are quite similar in Germany, as both work with health data. The Federal Ministry of Health has regulated the details of this procedure in the supplementary legal regulation, the Digital Health Applications Ordinance (Digitale Gesundheitsanwendungen-Verordnung, DiGAV). Further regulations are also given in Sections 33a and 139e of the German Social Code Book V (Fünftes Buch Sozialgesetzbuch, SGB V).

Denmark has requirements under development. A national board to assess apps is currently put in place. Certified applications will be displayed at the citizens health data portal (sundhed.dk).[69]

Italy is working at Guidelines on the Evolutionary Pathway of Medical Systems for Telemonitoring (Age.na.s., v1.0, 2024). The document aims to achieve the following objectives:

- outline the requirements that a Medical System must meet to ensure interoperability with the Regional Telemedicine Infrastructure, as mandated by the Ministerial Decree of September 21, 2022. This includes ensuring appropriate levels of certification and security.
- to provide an overview of the characteristics, requirements, recommendations and standards that need to be considered when defining an evolutionary path for Medical Systems.

The Guideline is intended primarily for Manufacturers and Distributors of medical devices as well as health organization/authorities and Regions/ Autonomous Provinces.

Sweden

Nationella medicintekniska informationssystem (NMI) covers software developed for common use at national, regional or municipal level, which handles data for the benefit of individual patients without performing an action on the data and are therefore not medical devices according to MDCG 2019-11. They are subject to a separate national legislation, currently HSLF-FS 2022:42. The current legislation entered into force 1 August 2022 and is harmonised with MDR and is a substantial revision from the previous legislation (LVFS 2014:7) based on the MDD. The systems need to be marked with NMI similar to the MD or IVD mark for medical devices. It includes parts from MDR Annex I, Chapter III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE - Label and instructions for use. The legislation includes requirements on post market surveillance and vigilance for NMI placed on the market.[70]

[68] https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Nursing-Applications/_node.html

[69] ttps://www.sundhed.dk/borger/sygdom-og-behandling/om-sundhedsvaesenet/anbefalede-sundhedsapps/

[70] https://www.lakemedelsverket.se/en/medical-devices/surveillance-vigilance#hmainbody1

Aside from Member State initiatives commercial suppliers of wellness applications assessment include e.g. the Organisation for the Review of Care and Health Apps (ORCHA)[71], which was also partner in the Label2Enable project.

[71] https://orchahealth.com

4. EHDS REQUIREMENTS FOR WELLNESS APPLICATIONS

The purpose of this chapter is to analyse what requirements apply for wellness applications for which interoperability has been claimed by the manufacturer, which is combined as per the Task 8.3 description with a further evaluation of the applicability of CEN-ISO/TS 82304-2 in providing a basis for the EHDS scheme for wellness applications, considering the EU regulations in place, and the relevance of the Label2Enable conformity assessment scheme ('the handbook'). This will result in a set of guidelines for app manufacturers to be compliant with the new regulation requirements, which will be on display in Chapter 5.

With regard to considering the EU regulations in place, the Label2Enable handbook was already aligned with the main EU level legislation applicable to health apps, i.e., the Medical Device Regulation (MDR) and the General Data Protection Regulation (GDPR). As at the time a final version of the EHDS was not available a full alignment with the EHDS was not achievable. Nonetheless, the handbook does include to some extent information related to the EHDS. This content will be updated as well as a result of the analysis in this chapter.

This chapter contains three parts. These include (1) the requirements that are specific to wellness applications detailed in Articles 47 to 49, which are as they solely apply to wellness applications not covered in D5.1, (2) the requirements from Annex II which entails an interpretation of the extent to which this Annex applies or can be interpreted to apply ("mutatis mutandis") for wellness applications, and (3) a mapping with the European ethical principles. A review of the D5.1 interpretation and its relevance for wellness applications to support in time alignment is included in **Appendix II**. The content includes a mapping which CEN-ISO/TS 82304-2 requirements relate to the relevant EHDS content and as such may support establishing compliance of wellness applications with the EHDS. This may aside from manufacturers, and conformity assessment bodies, also support market surveillance authorities [Article 47(7)].

4.1 Wellness application specific requirements [Article 47 to 49]

Inspired by D5.1 and taking into account upcoming feedback rounds from Member States and manufacturers, this chapter lists per separate applicable paragraph of Article 47 to 49:

(1) the original EHDS text,

(2) for the most part intentionally literally the mandatory requirements, with changes only reflecting the perspective of the manufacturer for whom guidance is to be created, avoiding repetitions by addressing requirements where most suited given the purpose of a section,

(3) if applicable, our interpretation based on referenced parts of the EHDS (which deviates from the approach with objectives D5.1 used), again applying the perspective of manufacturers and their likely information needs as a basis for the guidelines in Chapter 5,

(4) if applicable, recommended features / best practices.

The interpretations have been aligned with the responses to the frequently asked questions and have as such guided the current version of the guidelines (see Chapter 5). The clarity of the guidance will be enhanced with the results of feedback from manufacturers and other relevant stakeholders that is intended to be gathered in September 2025.

4.1.1 Article 47(1)

> **"Where a manufacturer of a wellness application claims interoperability with an EHR system in relation to the harmonised software components of EHR systems and therefore compliance with the common specifications referred to in Article 36 and essential requirements laid down in Annex II, such wellness application shall be accompanied by a label, clearly indicating its compliance with those specifications and requirements. That label shall be issued by the manufacturer of the wellness application."**
>
> **Article 47(1)**

Mandatory requirement

(i) Where a manufacturer of a wellness application claims interoperability with an EHR system in relation to the harmonised software components of EHR systems, and therefore compliance with the common specifications referred to in Article 36 and essential requirements laid down in Annex II, the manufacturer of the wellness application **shall** issue a label, clearly indicating its compliance with those specifications and requirements.

Interpretation

Claiming interoperability with an EHR system in relation to the harmonised software components of EHR systems is linked to the definition of the European interoperability software component [Article 2.2(n)] which is interpreted as a need for wellness application manufacturers to use the European electronic health record exchange format (EEHRxF).

> **'European interoperability software component for EHR systems'** means a software component of the EHR system which provides and receives personal electronic health data under a priority category for primary use established under this Regulation in the European electronic health record exchange format provided for in this Regulation and which is independent of the European logging software component for EHR systems;
>
> Article 2.2(n)

See for compliance with the common specifications referred to in Article 36 and essential requirements laid down in Annex II Paragraph 4.2.

What being accompanied by a label means is further detailed in Article 47(6),(8) and (9) and thus not included here as a mandatory requirement. Issuing a label was interpreted as self-declaration, and not third-party assessment (certification) or validation [Recital 49].

Recommended features / best practices

(i) We expect the implementing acts, and/or if applicable further clarification from the EC to:

- specify the design and content of the label [Article 47(3)] to an extent that a manufacturer merely needs to fill out a limited set of data fields,
- indicate how manufacturers can ensure the label is drawn up in an accepted language for each Member State where the wellness application is placed on the market or put into service [Article 47(4)],
- specify the what is assumed to be a standard validity period and not a validity period that a manufacturer has to decide upon [Article 47(5)],
- provide further guidance on what is considered a significant change in the design and intended use of a wellness application that would affect the validity period and require the manufacturer to take appropriate specified action, what follow-up is expected if a market surveillance authority discovers non-compliance, as well as what would be expected after the label expires.

(ii) Similar to e.g., the EU Energy label[72], the competent authority or another entity provides a generator for the label, which ensures the manufacturer fills out all specified data fields [Article 47(2)], and the format and content comply with the specifications [Article 47(3-6)], avoiding each manufacturer having to fabricate their own label generator. This could for instance be a service of the EU database for registration of EHR systems and wellness applications, which could then also display the label to enhance transparency.

(iii) If market-surveillance authorities use certain tooling to establish compliance, good to consider making these available so wellness application manufacturers can check compliance themselves.

[72] https://foodlabelmaker.com/regulatory-hub/ec/eu-nutrition-labels/

(iv) Guidance on requirements for verifying third-party data quality and security, clarification of responsibility when interoperating with external platforms, Guidance on managing risks from third-party SDKs/APIs.

4.1.2 Article 47(6)

> **"If the wellness application is an integral part of a device or is embedded in a device after it has been put into service, the accompanying label shall be shown in the application itself or placed on that device. Where the wellness application consists only of software, the label shall have a digital format and shall be shown in the application itself. Two-dimensional (2D) barcodes may also be used to display the label."**
>
> **Article 47(6)**

Mandatory requirements

(i) If the wellness application is an integral part of a device or is embedded in a device after it has been put into service, the accompanying label **shall** be shown in the application itself or placed on that device.

(ii) Where the wellness application consists only of software, the (digital version of the) label **shall** be shown in the application itself.

Interpretation

Shall have a digital format was rephrased to the (digital version of the) label, to focus on the role of the manufacturer (shall be shown in the application itself, which requires a digital format) and less so the role of the implementing act (shall have a digital format).

The two-dimensional barcode requirements are expected to be further specified in the implementing acts [Article 47(3)].

Recommended features / best practices

(i) The label should be readily available, i.e., hard for a user to miss. The implementing acts and ideally the label generator should incorporate guidance as to size and location of the label or features that prevent inadequate displays. To consider whether an adequate location would be in close proximity of the features that enable a natural person to choose categories of health data to insert and related circumstances [Article 48(2)]. This guidance could potentially build and expand on the results of Task 5.3 of the Label2Enable project (display of the CEN-ISO/TS 82304-2 label in the context of an app store - D5.3) and, if considering the CEN-ISO/TS 82304-2 label as a basis for the EHDS label, CEN-ISO/TS 82304-2's normative annex A, which was inspired by the EU energy label guidance, and Task 4.3 of the Label2Enable project and its article detailing usability testing of the CEN-ISO/TS 82304-2 label in four corners of Europe (France,

Hungary, Italy, Sweden) (D4.2) which is expected be submitted for publication Q3/Q4 2025. In general, consulting and incorporating existing knowledge of effective labelling is recommended.[737475]

(ii) Based on the findings of T4.4 (D4.3) of the Label2Enable project, short educational videos on the EHDS label, co-created and tested with persons with low health literacy should be made readily available to support inclusivity [Recital 7]. An eye tracking study and talking versions of the label (targeted at persons with visual disabilities or reading issues) were recommended as a follow-up for the CEN-ISO/TS 82304-2 label.

4.1.3 Article 47(8)

> **"Each supplier of a wellness application for which a label has been issued shall ensure that the wellness application that is placed on the market or put into service is accompanied by the label for each individual unit, free of charge."**
>
> **Article 47(8)**

Mandatory requirements

(i) Each supplier of a wellness application for which a label has been issued **shall** ensure that the wellness application that is placed on the market or put into service is accompanied by the label for each individual unit, free of charge.

Interpretation

A supplier is not defined in the EHDS or MDR and only referred to in this paragraph. The definition in Regulation (EU) 2017/1369 (setting a framework for energy labelling) for a supplier is: a manufacturer established in the Union, the authorised representative of a manufacturer who is not established in the Union, or an importer who places a product on the Union market. As such this article is presumed to be applicable to manufacturers and thus to be part of the guidelines in Chapter 5.

Recommended features / best practices

(i) Having a label accompany each individual wellness application free of charge, would imply a possible label generator to be free of charge as well.

[73] https://www.eca.europa.eu/en/publications?ref=SR-2024-23

[74] https://energy-efficient-products.ec.europa.eu/ecodesign-and-energy-label/understanding-energy-label_en

[75] https://op.europa.eu/webpub/eca/special-reports/eu-energy-labels-1-2020/en/

4.1.4 Article 47(9)

> **"Each distributor of a wellness application for which a label has been issued shall make the label available to customers at the point of sale in an electronic form."**
>
> **Article 47(9)**

Mandatory requirement

(i) Each manufacturer of a wellness application for which a label has been issued **shall** supply the label to their distributors to enable them to make the label available to customers at the point of sale in an electronic form.

Interpretation

The EHDS defines distributor as any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market. As these guidelines focus on manufacturers, we have adjusted the mandatory requirement to apply to the manufacturer as opposed to the distributor.

Examples of distributors include the app stores, repositories or app libraries with links that enable a user to download an application. Such stores and repositories may be commercial, such as the Apple or Google stores, but in the healthcare domain also include access points for applications run by healthcare provider organisations in the public, private and not-for-profit sector. The manufacturer of the wellness application will have to ensure that such services are able to use the label they provide.

'In an electronic form' was considered equal to digital format [Article 47(6)] and alongside the use of a 2D barcode to become sufficiently clear from the implementing acts [Article 47(3)].

All of the Article 47 mandatory requirements can be addressed in quality requirement **5.5.2.1** of the Label2Enable handbook for CEN-ISO/TS 823042, see Chapter 5.

4.1.5 Article 48(1)

> **"Manufacturers of wellness applications may claim interoperability with an EHR system, provided that the common specifications and essential requirements referred to in Article 36 and Annex II, respectively, are met. In the event of such claim, those manufacturers shall duly inform users of the interoperability of such wellness applications and the effects of such interoperability."**
>
> **Article 48(1)**

Mandatory requirements

(i) Where manufacturers of wellness applications claim interoperability with an EHR system, they **shall** meet common specifications and essential requirements referred to in Article 36 and Annex II, respectively.

(ii) In the event of such a claim, those manufacturers **shall** duly inform users ("natural persons") of the interoperability of such wellness applications and the effects of such interoperability.

Interpretation

Duly inform is considered a narrative text or links to such, that:

- is readily available, i.e., hard for a user to miss, in the app, in the related website and potentially also in the app store description of the app,
- explains briefly and understandably all relevant information the user needs to be informed about:
  - the data categories that can be shared,
  - if applicable, which types of EHR systems are supported, (those with patient summaries that include patient-provided data, and not e.g., CT-scanners, other distinctions?)
  - how these categories of health data of this specific wellness application for which interoperability has been claimed if inserted in their own electronic health record [Article 5] could be useful [Recital 49] and what use could be made of it, referring to reliable sources, if available, to support the claim of usefulness and raising awareness to any risks, contra-indications and limitations of use, if available referring to relevant European medical society guidelines,
  - how a user is able to choose which categories of data from the wellness application are to be inserted in their own EHR and the circumstances for the sharing or transmission of those categories of data, that actual sharing of data is only possible after the user has given consent and that the interoperability shall be limited exclusively to those purposes [Article 48(2)],
  - how the interoperability works, e.g., privacy aspects of the interoperability, that these data will be labelled in the EHR as patient-provided data [Article 5], that health professionals who are authorised to access their EHR can see it there and may take it into consideration, and that an anonymised or pseudonymised version [Article 66(2-3)]of these data [Article 51.1(i)] may also

be made available for purposes that would benefit society, such as research, development and policy [Article 53(1), Recital 1].

These mandatory requirements can be addressed in quality requirement **5.3.2.5** of the Label2Enable handbook for CEN-ISO/TS 82304-2, see Chapter 5, or alternatively **5.5.2.1** to avoid having to duplicate an explanation of the EHDS. Of note is that CEN-ISO/TS 82304-2 5.3.2.5 is the quality requirement with by far the most assessment sub-questions, an issue which has been flagged to be addressed in the upcoming revision of CEN-ISO/TS 82304-2.

Recommended features / best practices

(i) With regard to usefulness of wellness application data for healthcare purposes [Recital 49], the Label2Enable interview study with Catalan and Italian health authority representatives confirmed that not all data generated by apps are clinically relevant, with relevance generally differing per pathology and care pathway.[76] Guidance from European medical societies as to which data is useful should be encouraged to support manufacturers, users and health professionals in their ideally aligned decision-making on which categories of personal electronic health data to claim interoperability for, insert and use.

(ii) Although technically Article 48 does not apply for medical devices, expanding the CEN-ISO/TS 82304-2 note and assessment sub-question to include medical devices may be considered to adequately also inform users of medical devices that are generally used as consumer products, e.g. (the widely used) fertility apps (class IIb) which may provide useful information for e.g. gynaecologists in specific use cases.[77]

(iii) An example or template to standardize a duly inform-message would support manufacturers in creating an adequate version of such message.

(iv) Consider if this information needs to be available in the local language.

4.1.6 Article 48(2)

"The interoperability of wellness applications with EHR systems shall not entail the automatic sharing of all or part of the health data from the wellness application with, or automatic transmission of all or part of such data to, the EHR system. The sharing or transmission of such data shall only be possible if it is in accordance with Article 5 and after consent is given by the natural person concerned and interoperability shall be limited exclusively to those purposes. The manufacturers of wellness applications claiming interoperability with an EHR system shall ensure that the natural person concerned is able to choose which categories of health data from the wellness application are to be

[76] https://formative.jmir.org/2025/1/e67855

[77] https://obgyn.onlinelibrary.wiley.com/doi/10.1111/ajo.13781

inserted in the EHR system and the circumstances for the sharing or transmission of those categories of data."

Article 48(2)

Mandatory requirements

(i) The interoperability of wellness applications with EHR systems **shall not** entail the automatic sharing of all or part of the health data from the wellness application with, or automatic transmission of all or part of such data to, the EHR system.

(ii) The sharing or transmission of such data **shall** only be possible if it is in accordance with Article 5 and after consent is given by the natural person concerned.

(iii) Interoperability **shall** be limited exclusively to those purposes.

(iv) The manufacturers of wellness applications claiming interoperability with an EHR system **shall** ensure that the natural person concerned is able to choose which categories of health data from the wellness application are to be inserted in the EHR system and the circumstances for the sharing or transmission of those categories of data.

Interpretation

Categories of health data from a wellness application inserted in an EHR were considered a subcategory of patient-provided *information* [Article 5], and to equal patient-provided *data* [Annex I.1.15], given the use of the EEHRxF which according to the definition of the European interoperability software component is intended for priority data, the non-clinical purpose of wellness applications which rules out other types of priority data, and given its digital form (as per the definition of data) for which no other source was found than wellness applications. Furthermore, Recital 49 specifically points to the "capability of those (wellness) applications to export data in an interoperable format", which also implies the use of the EEHRxF in relation to the priority categories of personal electronic health data, and that such data from wellness applications is expected to land in the patient summary under the heading patient-provided data.

It is important to note that the Guidelines on Patient Summary, Release 3.4 from November 2024 by the eHealth Network[78] clearly state that the specifications for the patient summary are not ready yet to accept such data from wellness applications. The document states that "the patient provided data section is a section for data reported **by a health professional** after provision of additional information from the patient, like a travel history relevant for the Patient Summary (e.g. recent travel in a region of high prevalence of a specific infectious disease like Malaria). The section is not intended for data injected directly by the patient. Future revisions of the Patient Summary Guidelines might capture the need of such

[78] https://health.ec.europa.eu/document/download/e020f311-c35b-45ae-ba3d-03212b57fa65_en?filename=ehn_guidelines_patientsummary_en.pdf

reported data." Please find further considerations and suggestions on this topic in Chapter 6 of this document.

In accordance with Article 5 was interpreted as requiring that the manufacturer enables the user to exercise their right to insert data from a wellness application in their own EHR [Article 5], by allowing a user to choose which data to insert under which circumstances after consent (and after being duly informed [Article 48(1)]). The EHR system needs to label the data as patient-provided and accept data in an EEHRxF. The wellness application manufacturer needs to use the EEHRxF. This likely means the EEHRxF includes a data field meta labelling the data as patient-provided, capturing perhaps further information such as the quality of the wellness application and origins of the data (sensor, manual input by user, manual input by proxy, other source, such as EHR or another app). Via this route (use of EEHRxF to insert wellness application data) a user altering electronic health data and related information by health professionals that already sit in the EHR seems technically not feasible.

These mandatory requirements can be addressed in quality requirement **5.4.1.1.6** of the Label2Enable handbook for CEN-ISO/TS 82304-2, see Chapter 5, or alternatively in **5.5.2.1**, to avoid having to duplicate an explanation of the EHDS.

Recommended features / best practices

(i) Giving consent as a legal base for data processing as per GDPR also implies being able to withdraw consent at any time or change the choice of categories of health data and / or circumstances, ensuring adequate follow-up for these decisions.

(ii) Consider if this information needs to be available in the local language.

(iii) Consider clarifications if a wellness application inserts data more than once in the same EHR system. Is overlapping data allowed, or can new data only supplement previously inserted data? If overlapping data is allowed, are EHR systems allowed to remove the older version of the data to avoid excessive use of space?

(iv) Consider providing an informed consent form template in the manufacturer guidelines in all official EU languages.[79]

[79] An example of a multi-lingual informed consent form template created for the European Reference Network: https://www.ern-rnd.eu/cpms/download-consent-forms/

4.1.7 Article 49(2)

> **"Before placing on the market or putting into service an EHR system referred to in Article 26 or a wellness application referred to in Article 47, the manufacturer of such EHR system or wellness application or, where applicable, its authorised representative shall enter the required data as referred to in paragraph 4 of this Article into the EU database for registration of EHR systems and wellness applications, including in the case of EHR systems, the results of the assessment referred to in Article 40."**
>
> **Article 49(2)**

Mandatory requirement

(i) Before placing on the market or putting into service a wellness application referred to in Article 47, the manufacturer of such wellness application **shall** enter the required data as referred to in paragraph 4 of this Article, into the EU database for registration of EHR systems and wellness applications.

Interpretation

Where applicable its authorised representative was considered to apply to EHR systems and not to wellness applications, as this distinction was not made in Article 47(1) or elsewhere.

This mandatory requirement can be addressed in quality requirement **5.5.2.1** of the Label2Enable handbook for CEN-ISO/TS 82304-2, see Chapter 5.

Recommended feature / best practice

(i)t Filling out the database could include automated tooling to establish compliance beyond a doubt, or if not available, an online tool with clear pass / fail indicators and boxes to tick to enable also startups to easily establish compliance.

(ii) The register is expected to display the label or which interoperability a confirmed wellness application supports, e.g., which types of data. Some respondents in the consultation stressed the need for a database that gathers compliant wellness apps, not only from an interoperability point of view, complementing EUDAMED.

(iii) Providing guidance how to comply could include wireframes or UX patterns for interoperability decision-making, consent management, duly inform messaging and label display, that meet accessibility requirements (e.g., for visually impaired users) and UX best practices for multilingual, pan-European deployment, and support easy recognition and actionability for users.

(iv) It is important to ensure that the data/information that falls within the scope of supervision is structured in a way that makes it easy to access by the relevant supervisory authorities. For the same

reason, information about/contact details to the legal person/person responsible for each product, service or similar also needs to be easily accessible and kept up to date.

4.2 Annex II and its applicability for wellness applications

4.2.1 Meaning *mutatis mutandis*

Annex II of the EHDS is titled "Essential requirements for the *harmonised software components of EHR systems* and for *products* for which interoperability with EHR systems has been claimed". The subtitle states that "the essential requirements laid down in this Annex shall apply *mutatis mutandis* to medical devices, *in vitro* diagnostic medical devices, AI systems and *wellness applications* claiming interoperability with EHR systems."

Before looking at the three sets of requirements set out in Annex II it is important to explain how we have interpreted the term *mutatis mutandis*. The term is not unusual in EU law and is usually used when the legislator wants to signal that a legal rule or procedure developed for a particular context may be applied to another context by analogy. The term indicates that the core elements or objectives of the legislation remain the same, but that some adjustments (e.g., terminology, institutions, procedures, or scope) may be implied to make it fit the new context.

A review of the use of the term in other EU legislation and also reference to it in European Court of Justice rulings suggests that the term is usually interpreted narrowly, meaning that the rules address to the context named in the legislation will apply to the other context where there is a clear similarity of purpose or objective.

As the EHDS Regulation has not yet been clarified by delegated or implementing legislation nor interpreted by the ECJ we cannot be certain about how a future national or EU level court decision might interpret which requirements set out in Annex II will apply to wellness applications. However, given the usual narrow interpretation we believe that it is likely that only those aspects of Annex II which impact the way in which data from a wellness application is used in the EHDS will be applied, *mutatis mutandis*, to wellness apps. Where more than one interpretation of the term seems possible, we offer the interpretation scenarios, our reasoning and its rationale in 4.2.2.

Chapter 5 will provide guidance on how use of the requirements set out in CEN-ISO/TS 82304-2 can help wellness app manufacturers meet those requirements set out in Annex II which, *mutatis mutandis*, apply to wellness applications.

4.2.2 Interpretation *mutatis mutandis*

The Annex II Sections which were considered to (potentially) apply *mutatis mutandis* were color coded in Figure 7. An overview of the rationale behind it is included in Table 2.

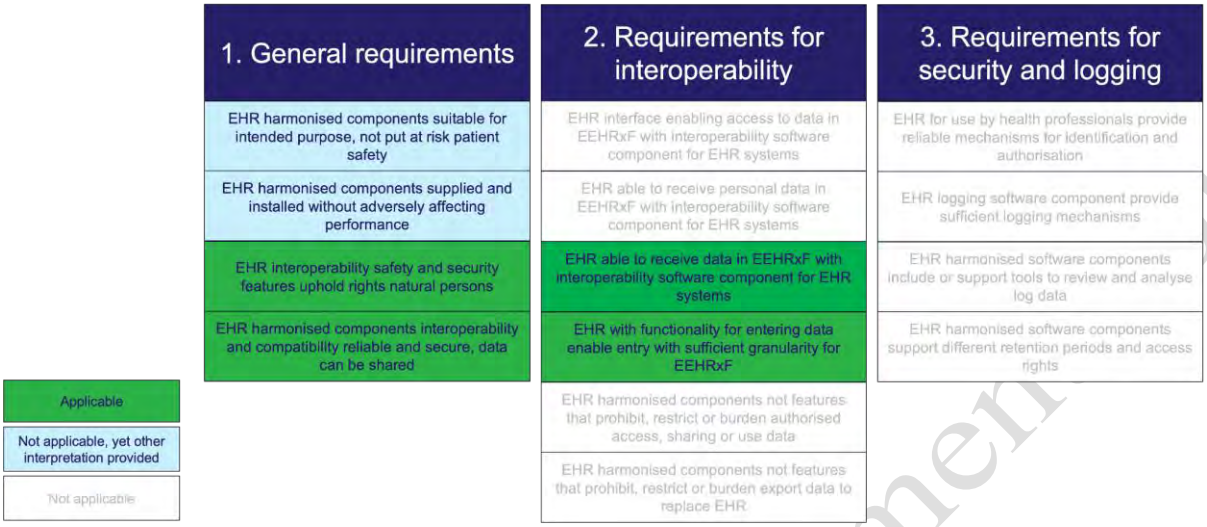

Figure 7 Overview interpretation mutatis mutandis Annex II

1410

1411 Table 2 Applicability of Annex II requirements for wellness applications

Applicability Annex II for wellness applications	
Annex II	**Interpretation *mutatis mutandis***
1.1 "**The harmonised software components of an EHR system** shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose and their use does not put at risk patient safety."	Not applicable
Reasoning: Does not apply as (1) the harmonised software components are specific to EHR systems (while EHR systems include it [Article 25], other products claim interoperability with it [Article 27, 47]), and (2) Recital 49 specifies that the compliance of wellness applications is about interoperability and security requirements, which is considered not to include suitability for the intended use of a wellness application. Member States may however regulate other aspects of the use of wellness applications [Recital 50].	
1.2 "**The harmonised software components of the EHR system** shall be designed and developed in such a way that the EHR system can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use."	Not applicable
Reasoning: Does not apply as (1) the harmonised software components are specific to EHR systems, and (2) Recital 49 specifies that the compliance of wellness applications is about interoperability and security requirements, which is considered not to include installation (download) and performance during intended use of a wellness application by the intended user. Member States may however regulate other aspects of the use of wellness applications [Recital 50].	
1.3 "An EHR system shall be designed and developed in such a way that its interoperability, safety, and security features **uphold the rights of natural**	Interpretation *mutatis mutandis*: "A wellness application for which the manufacturer has claimed interoperability with an EHR system shall be designed and developed in such a way that

persons, in line with the intended purpose of the EHR system, as set out in Chapter II."	its interoperability, safety, and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II and III."
Reasoning: Applies, given that Article 48(2) refers to Article 5, which is about 'the right of natural persons to insert information in their own electronic health record'. Moreover, Article 48(2) requires that the natural person must be able to choose which categories of health data to share under which circumstances. Such data sharing must be based on the consent of the natural person. The rights of the natural person to be upheld is specific to inserting information as defined in the EHDS but also the wider rights that are implicit in allowing data sharing i.e., the authenticity, integrity, and non-repudiation of the data that the patient wishes to share from the application to their EHR. This requires that adequate security features are used in the application.	
1.4 "The harmonised software components of an EHR system that is **intended to be operated together with other products, including** medical devices [D5.1: and **wellness applications**], shall be designed and manufactured in such a way that **interoperability and compatibility are reliable and secure**, and **personal electronic health data can be shared** between the device [D5.1: these devices] and the EHR system **in relation to those harmonised software components of an EHR system**."	Interpretation *mutatis mutandis:* "A wellness application that is intended to be operated together with the harmonised software components of an EHR system shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data the manufacturer intends to claim interoperability for can be shared between the wellness application and the EHR system."
Reasoning: Applies, as per Article 47(1) wellness applications can claim interoperability with an EHR system in relation to the harmonised software components. Reliable and secure interoperability and compatibility affect both the European interoperability software component of the EHR system and the wellness application: Article 2.2(n) explains the European interoperability software component receives (and provides) personal electronic health data in the EEHRxF, and Article 15(1) specifies that the EEHRxF shall allow transmission of personal electronic health data between software applications, devices (both interpreted to include wellness applications, which are by definition either software or a combination of software and hardware) and healthcare providers. Furthermore, Recital 49 refers to the capability of those wellness applications to export data in an interoperable format which also implies the use of the EEHRxF in relation to the harmonised components of EHR systems.	

2.1 "Where an EHR system is **designed to store or intermediate** personal electronic health data, it shall provide an **interface enabling access** to the personal electronic health data processed by it in the European health record exchange format, **by means of the European interoperability software component** for EHR systems."	Not applicable
Reasoning: Does not apply as designed to store and intermediate personal electronic health data and providing an interface to enable the natural person and health professionals to access data that was processed by means of the European interoperability software component are specific to EHR systems.	
2.2 "Where an EHR system is **designed to store or intermediate** personal electronic health data, it shall be able to **receive** personal electronic health data in the European health record exchange format, **by means of the European interoperability software component** for EHR systems."	Not applicable
Reasoning: Does not apply as designed to store and intermediate personal electronic health data by means of the European interoperability software component, without the EHR enabling access to natural persons [Annex II 2.3], are specific to the type of EHR systems that are unlikely to receive patient-provided data from wellness applications.	
2.3 "Where an EHR system is **designed to provide access** to personal electronic health data, it shall be **able to receive** personal electronic health data **in the European health record exchange format**, **by means of the European interoperability software component** for EHR systems."	Interpretation *mutatis mutandis:* "A wellness application for which the manufacturer has claimed interoperability with an EHR system shall export and supply personal electronic health data for which consent has been given in the European health record exchange format by means of the European interoperability software component for EHR systems."
Reasoning: Applies, as wellness applications claiming interoperability supply personal electronic health data to the EHR systems which are designed to provide access. To achieve interoperability and compatibility [Annex II Section 1.4] and uphold the right to insert information [Annex II Section 1.3], wellness applications need to use the EEHRxF to insert data in the user's own EHR by means of the European interoperability software component.	

2.4 "An EHR system that includes a functionality for **entering structured personal electronic health** data shall enable the entry of data with **sufficient granularity** to enable the provision of the entered personal electronic health data in the European health record exchange format. "	Interpretation *mutatis mutandis:* "A wellness application for which the manufacturer has claimed interoperability with an EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data with sufficient granularity to enable the provision of the entered personal electronic health data in the European health record exchange format."
Reasoning: To achieve interoperability and compatibility [Annex II Section 1.4] and uphold the right to insert information [Annex II Section 1.3] by means of the European health record exchange format, wellness applications need to capture data with sufficient granularity.	
2.5 The **harmonised software components** shall not include features that **prohibit, restrict or place an undue burden** on authorised access, personal health data sharing or use of personal electronic health data for permitted purposes.	Not applicable
Reasoning: Does not apply as (1) the harmonised components are specific to EHR systems, and (2) features that prohibit, restrict or place an undue burden on access, data sharing and use of data go beyond the concept of purpose-driven interoperability as per Article 48(2). Reliable and secure interoperability for wellness applications is covered in Annex II Section 1.4.	
2.6 "The **harmonised software components** of an EHR system shall not include features that prohibit, restrict or place an undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product."	Not applicable
Reasoning: Does not apply as the harmonised components and features that prohibit, restrict or place an undue burden for the reasons of replacing the EHR system are specific to EHR systems. (Data portability, e.g. if a device and potentially platform is replaced or if the app is uninstalled in favour of another product, is addressed in CEN-ISO/TS 82304-2 **5.5.2.4**.)	

3.1 An EHR system **designed to be used by health professionals** shall provide reliable mechanisms for the identification and authentication of health professionals.	Not applicable
Reasoning: Does not apply as by definition health professionals are not intended users of wellness applications, they get access to patient-provided data originating from a wellness application in the EHR system.	
3.2 "The European **logging software component** of an EHR system designed to enable **access by healthcare providers** or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record at least the following information on every access event or group of events [...]"	Not applicable
Reasoning: Does not apply as by definition wellness applications are not designed to enable access to healthcare providers or other individuals. Related logging is as such not applicable. Instead of data access, we do recommend considering logging data entry (user, proxy, sensor, other app) to support health professionals in considering patient-provided data.	
3.3 "The **harmonised software components** of an EHR system shall include tools or mechanisms to review and **analyse the log data**, or it shall support the connection and use of external software for the same purposes."	Not applicable
Reasoning: Does not apply as the harmonised components and logging which is related to health professional access are specific to EHR systems.	
3.4 "The **harmonised software components** of an EHR system that store personal electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.**"**	Not applicable
Reasoning: Does not apply as the harmonised components and access rights are specific to EHR systems. (Retention periods for wellness applications are addressed in CEN-ISO/TS 82304-2 5.4.1.1.3.) Guidance in the	

implementing legislation on how long patient-provided data shall or should be retained in the EHR would support the wellness app manufacturer to inform users on this topic ("duly inform" Article 48(1)).

4.2.3 Applicability of Annex II in more detail

Sections of Annex II with arguably more than one interpretation are elaborated in more detail below, considering the EU regulations in place. Also, how *mutatis mutandis* was interpreted if considered to apply and the CEN-ISO/TS 82304-2 requirements that can address the requirements are referenced here and then further detailed in Chapter 5.

4.2.3.1 Annex II Section 1.1

"The harmonised software components of an EHR system shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose and their use does not put at risk patient safety."

Annex II 1.1

In Table 2 in 4.3.1 we have stated that Section 1.1 does not apply. However, an alternative interpretation could be taken as follows. As the manufacturer has claimed interoperability with EHR systems, then *mutatis mutandis* could be interpreted as "Wellness applications shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose and their use does not put at risk patient safety." If this wider interpretation is taken, especially the CEN-ISO/TS 82304-2 **5.2** "healthy and safe" quality requirements may be considered.

An advantage of this alternative interpretation is that it could be helpful in building trust by users to consider inserting data and health professionals taking this patient-provided data into account, *provided* the labelling would entail certification.[80][81][82] It could also help to contribute to harmonisation instead of fragmentation of health data [Recital 7], and potentially enhance the uptake and reimbursement of health and wellness apps and nearly non-existent cross-border uptake of apps, again *provided* the labelling would entail certification.[83][84][85] This objective could however also - and given the expressed multi-stakeholder

[80] https://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-065.FINAL.CPME.position.EHDS.pdf
[81] https://academic.oup.com/ehjdh/article/5/5/509/7687695
[82] Label2Enable D4.1, D4.3, D5.3
[83] https://label2enable.eu/assets/downloads/la2en-infographic-recommendations-v5-1716569726.pdf
[84] https://www.nature.com/articles/s41746-024-01263-w
[85] https://mhealth.jmir.org/2023/1/e49003/

need for certification better - be achieved on a Member State level as Recital 50 states that Member States should remain free to regulate other aspects of the use of wellness applications, provided that the corresponding rules are in compliance with Union law. The Label2Enable handbook for CEN-ISO/TS 82304-2 was already aligned with the MDR and GDPR and has been aligned with the EHDS as a result of this effort. The results of an extensive comparative analysis by Catalonia of their framework and CEN-ISO/TS 82304-2[86] and uptake of the results of a comparative analysis with several European HTA frameworks in the Label2Enable handbook for CEN-ISO/TS 82304-2 seem to indicate adoption of CEN-ISO/TS 82304-2 would result in a limited number of required context specific requirements on top of CEN-ISO/TS 82304-2 and as such address the objective to reduce fragmentation [Recital 7]. Expert support to Member States in considering CEN-ISO/TS 82304-2 and potential context-specific requirements on top, analyses similar to Catalonia, would likely be needed to promote wider adoption for potentially health apps in general. The wider interpretation would align with the 2024 Product Liability Directive which has significantly extended the scope of application of EU consumer protection law to address also software, including standalone software, such as Software as a Medical Device (SaMD), and embedded software.

4.2.3.2 Annex II Section 1.2

> **"The harmonised software components of the EHR system shall be designed and developed in such a way that the EHR system can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use."**
>
> **Annex II 1.2**

In Table 2 in 4.3.1 we have stated that Section 1.1 does not apply. However, an alternative interpretation could be taken as follows. The manufacturer has claimed interoperability with EHR systems, and as the Article applies to EHR systems, *mutatis mutandis* would then be interpreted as "Wellness applications claiming interoperability with an EHR system shall be designed and developed in such a way that the wellness application can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use". If this alternative interpretation would be considered to apply, especially CEN-ISO/TS 82304-2 **5.3** "Easy to use" quality requirements may be considered.

This wider interpretation would align with Recital 1 which sets the objective of the Regulation as improving natural persons' control over their data, allowing health data to be used for the benefit of society and supporting a better functioning of the internal market, in conformity with Union values. This could also be achieved on a Member State level and facilitated with the type of support indicated at Annex II Section 1.1.

[86] https://mhealth.jmir.org/2025/1/e67858

Of note, if Annex II 1.1 would be considered applicable, in our opinion Annex 1.2 should be considered applicable as well and vice versa.

4.2.3.3 Annex II Section 1.3

> **"An EHR system shall be designed and developed in such a way that its interoperability, safety, and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II."**
>
> **Annex II 1.3**

In Table 2 in 4.3.1 *mutatis mutandis* was interpreted as "A wellness application for which the manufacturer has claimed interoperability with an EHR system shall be designed and developed in such a way that its interoperability, safety, and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, within the context of Chapter II and III."

The right to uphold is Article 5 which gives natural persons the *right* to insert information in their own EHR, which may be achieved by a wellness application, provided that the manufacturer has claimed interoperability with an EHR system. Of note, Article 3 is not applicable as while the data sits in the wellness app, it is not a priority category. It will become part of a priority category *after* being inserted into an EHR. Chapter III of the EHDS Regulation was added to the *mutatis mutandis* description given Article 48(2), which requires that the natural person must be able to choose which categories of health data to share under which circumstances. Such data sharing must be based on the consent of the natural person. These rights were already addressed in the guidelines (Chapter 5) as a result of our analysis of Articles 47 to 49 in Chapter 4.2.

What is debatable is how wide interoperability, safety and security features should be interpreted. Features are not defined in the EHDS. ISO/IEC/IEEE 24765:2017 defines a *software* feature as a *software* characteristic specified or implied by requirements documentation (for example, functionality, performance, attributes, or design constraints). CEN-ISO/TS 82304-2 has quite a few interoperability, safety and security requirements that may fit the description in part or in full. Of note, D5.1 focuses on interoperability features, not security or safety features, but does refer to broader legal obligations for rights of natural persons under EHDS Chapter II and data protection regulations (example: GDPR, national regulations on personal data). Also given "considering the EU regulations (legislation) in place" [Task 8.3 assignment] and "uphold rights" [Annex II Section 1.3], we have interpreted the interoperability, safety and security features to be adequate if compliant with all relevant applicable EU level regulations relating to interoperability, safety and security. This entails that as set out in Chapter 3 of this Deliverable for wellness applications for which interoperability has been claimed, on top of the EHDS, manufacturers needs to consider to what extent GDPR, the ePrivacy Directive, GPSR, Cyber Resilience Act, the AI Act and other relevant EU legislation as well as complimentary Member State laws are applicable to them, if at all.

We flag however in particular for safety and security requirements the risk of self-declaration of these requirements. Third-party assessment (if possible) would encourage multi-stakeholder trust to use the application and its data as intended. Automated assessments would mitigate this risk and contribute to efficiency and quality of assessments. Therefore, using the digital testing environment [Article 40] to test the interoperability requirements would be beneficial for wellness applications. An initial analysis of automated assessments (prior to the EHDS) was done in Label2Enable, which indicated these do exist especially for accessibility, privacy and security requirements and, increasingly following EHDS and D5.1 provisions, for interoperability requirements. Their use could support and enhance both self-declaration and third-party assessment and as such effectively remove the difference between the two.

Outside the rights created for the natural person under EHDS, the natural person retains their GDPR rights which include access, correction and rectification of data collected by the wellness app and held by the data controllers of that data. These rights must be respected by the wellness app manufacturer as data controller of the wellness app; this obligation does not form part of the general requirements under EHDS. The right to access, correction and rectification of data which originated from the wellness app but have been included into the EHR must be respected by the EHR data controller.

Interoperability features

Interoperability features that may be considered on top of the already flagged CEN-ISO/TS 82304-2 **5.5.2.1** (APIs), include **5.5.2.2** (terminologies) and **5.5.2.3** (validation data imported in an app), the latter could also be considered a safety feature and is as such flagged for GPSR compliance.

Safety features

The CEN-ISO/TS 82304-2 requirements **5.2.2.1** (analysis health risks), **5.2.2.2** (measures to control health risks), **5.2.2.3** (residual health risks found acceptable), **5.2.2.5** (users made aware of health risks, contra-indications and limitations of use), and **5.2.2.6** (process to collect and review safety concerns and incidents), **5.4.2.2** (information security risk assessment), **5.4.2.3** (secure by design), **5.4.2.4** (third-party libraries and components reliable), **5.4.2.9** (security vulnerability management), and **5.5.2.3** (validation data imported in an app) are considered linked to GPSR compliance (safety requirements) based on a quick scan. CEN-ISO/TS 82304-2 requirement **5.2.4.2** (users made aware of health interventions), if applicable, is considered linked to AI Act compliance.

Security features

Within the Label2Enable project the following CEN-ISO/TS 82304-2 Secure data quality requirements were considered linked to GDPR compliance: **5.4.1.1.2** (data minimisation), **5.4.1.1.3** (retention policy), **5.4.1.1.4** (privacy statement), **5.4.1.1.6** (opt-in for sharing data with third parties), **5.4.1.1.8** (security-incident response procedures), **5.4.2.3** (secure by design), **5.4.2.6** (organisational measures), **5.4.2.7** (authentication, authorisation, session management), and **5.4.2.8** (encryption).

Depending on the app (app uptake, data processed, parties involved in data processing and the manufacturer), **5.4.1.1.5** (contracts with processors and controllers), **5.4.1.1.7** (Data Protection Officer), **5.4.2.2** (information security risk assessment), **5.4.2.9** (security vulnerability management) and **5.5.2.4** (data export) may apply as well. We did not scrutinise the Cyber Resilience Act but expect adding **5.4.2.9** (security vulnerability management) would address the aims of this Act, which given Recital 112 was considered applicable.

This *excludes* the CEN-ISO/TS 82304-2 Secure data quality requirements **5.4.2.1** (ISO 27001 or equivalent), **5.4.2.4** (third-party libraries and components reliable), **5.4.2.5** (process to prevent unauthorized access to source code), **5.4.2.10** (security tested on a regular basis and at major changes), and **5.4.2.11** (information security policy readily available). Even though for instance ISO 27001 was mentioned in the survey (**Appendix I**). This could prove a context-specific additional requirement, or if proven to apply for a significant number of Member States, become a European harmonised requirement. This could apply to more CEN-ISO/TS 82304-2 requirements, for instance the Web Content Accessibility Guidelines (WCAG), were also mentioned by several Member States in the survey (**Appendix I**).

CEN-ISO/TS 82304-2 requirement **5.4.1.1.6** (opt-in for sharing data with third parties), is considered linked to ePrivacy Directive compliance, which may however not be considered a security but rather a privacy feature.

Recommended feature / best practice

(i) Provide clarity on the (harmonised) scope of interoperability, safety and security features, both for manufacturers and market surveillance authorities, taking into account above remarks on the intent of Article 5, needs of health professionals and users of wellness applications, CEN-ISO/TS 82304-2 requirements, D5.1, as well as risks on self-declaration, and possible erosion of trust in CEN-ISO/TS 82304-2 labelling, which could be mitigated as proposed in Section 5.2 of this deliverable. Of note, in the current situation, manufacturers of wellness applications that are made available on the Union market, are to comply with European law without any mandatory labelling.

4.2.3.4 Annex II Section 1.4

> **"The harmonised software components of an EHR system that is intended to be operated together with other products, including medical devices [D5.1: and wellness applications], shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device [D5.1: these devices] and the EHR system in relation to those harmonised software components of an EHR system."**
>
> **Annex II 1.4**

In Table 2 in 4.3.1 *mutatis mutandis* was interpreted as "A wellness application that is intended to be operated together with the harmonised software components of an EHR system shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data the manufacturer intends to claim interoperability for can be shared between the wellness application and the EHR system."

"Personal electronic health data can be shared" is addressed in quality requirement **5.5.2.1** (APIs) of the Label2Enable handbook for CEN-ISO/TS 82304-2, see Chapter 5, and could as well be interpreted as including **5.5.2.2** (terminologies) as to be further detailed in the EEHRxF. As previously specified, wellness applications that claim interoperability have to use the EEHRxF (and have an API to enable the export of data).

What is debatable is the scope of reliable and secure. Reliable and secure are addressed within CEN-ISO/TS 82304-2 in particular within the quality aspects Secure data and Robust software. Given the direct relation with D5.1, we have flagged the CEN-ISO/TS 82304-2 requirements that relate to the requirements detailed in D5.1 in Figure 8. Secure seems at the minimum to include CEN-ISO/TS 82304-2 **5.4.2.8** (encryption), a potentially broader interpretation than D5.1, focusing on interoperability and compatibility and not a wellness application as a whole, could include **5.4.2.2** (information security risk assessment), **5.4.2.3** (secure by design), **5.4.2.4** (reliable third-party software libraries and components), **5.4.2.9** (security vulnerabilities identified and resolved), **5.4.2.10** (security tested on a regular basis and at major changes), **5.5.1.1** (health app requirements documented), **5.5.1.2** (health app developed with standards), **5.5.1.3** (secure coding), **5.5.1.4** (configuration management plan), **5.5.1.5** (processes to deal with increase or spike in demand), **5.5.1.6** (validation and verification plan), **5.5.1.7** (release and deployment process, and **5.5.1.8** (maintenance process).

Recommended features / best practices

(i) Provide clarity on the (harmonised) scope of reliable and secure, both for manufacturers and market surveillance authorities, taking into account that any combination of hardware and software referred to in the wellness application definition, which may refer to a multitude of different hardware products compatible with the wellness application software, that an individual natural person may choose from and replace over time.

(ii) Implementation should be easy and low-threshold from the manufacturers point of view in order to promote wellness applications that can provide useful information to claim interoperability with an EHR system, thus supporting the right of natural persons to insert information in their own EHR as described in Article 5.

(iii) Interoperability and compatibility are reliable and secure may also refer to third-party suppliers contracted by the wellness app manufacturer involved in the operations referred to.

4.2.3.5 Annex II Section 2.3

> **"Where an EHR system is designed to provide access to personal electronic health data, it shall be able to receive personal electronic health data in the European health record exchange format, by means of the European interoperability software component for EHR systems."**
>
> **Annex II 2.3**

In Table 2 in 4.3.1 *mutatis mutandis* was interpreted as "A wellness application for which the manufacturer has claimed interoperability with an EHR system shall export and supply personal electronic health data for which consent has been given in the European health record exchange format by means of the European interoperability software component for EHR systems."

The use of the EEHRxF is necessary if the user is to be able to exercise their right to insert data of their choice into their EHR. This requirement has been addressed in quality requirement **5.5.2.1** of the Label2Enable handbook for CEN-ISO/TS 82304-2, see Chapter 5.

Recommended features / best practices

(i) The EEHRxF is expected to have an identifier that ensures the data of the wellness app user lands in the EHR of the same natural person in the EHR system intended. To consider eIDAS-compliant identity providers or similar trusted ID services.

(ii) Close coordination with national standards – such as HL7 Europe Implementation Guides – can create synergies and significantly improve the technical connectivity of the EEHRxF.

(iii) FHIR is the to-be standard for mobile applications. HL7V3 and earlier are not suitable for modern mobile applications.

(iv) Add guidance encouraging adoption of scalable trust models that include app-level trust mechanisms. In the current situation establishing large-scale trust frameworks is hindered by the need for every app to get individual API keys. Approaches like UDAP (Security for Scalable Registration, Authorization and Authentication, used in the US) could address this. Using the European approach with OpenID connect is not including app-level pre-approval mechanisms that a certification program could enable. In the Netherlands the Trust Framework problem was solved with MedMij. MedMij is authorized by EHRs and gets access to the API. The user of the app has to be known in the EHR system. In Epic this is arranged with a MyChart account. For an app to be accepted to MedMij a procedure including testing is warranted.

(v) A feature that enables an EHR system to easily (automatically) recognise that the wellness application has indeed self-declared compliance with the common specifications referred to in Article 36 and essential requirements laid down in Annex II and that a market surveillance authority has not in the meantime discovered non-compliance temporarily or indefinitely withdrawing the label [Article 47(7)]. Does the wellness application upon registering in the European database for registration of EHR systems and

wellness applications get an identifier and that is then to be included in the EEHRxF and recognised as compliant / valid or not?

4.2.3.6 Annex II Section 2.4

> **"An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data with sufficient granularity to enable the provision of the entered personal electronic health data in the European health record exchange format."**
>
> **Annex II 2.4**

In Table 2 in 4.3.1 *mutatis mutandis* was interpreted as "A wellness application that includes a functionality for entering structured personal electronic health data and claims interoperability with an EHR system shall enable the entry of data with sufficient granularity to enable the provision of the entered personal electronic health data in the European health record exchange format."

This requirement has been addressed in quality requirement **5.4.1.1.2** of the Label2Enable handbook for CEN-ISO/TS 82304-2, see Chapter 5. Given D5.1 further specifications to CEN-ISO/TS 82304-2 **5.3.2.4** may be appropriate, these can be processed once more on the EEHRxF and granularity becomes clear.

Recommended feature / best practice

(i) Sufficient granularity should be defined based on or in accordance with the existing medical nomenclature (e.g. SNOMED CT) This may also include a differentiation between aggregated and raw data.

4.3 A checklist of actions to be performed to operate in a secure and ethical way within the EHDS

Whereas security has been scrutinised in the previous paragraphs, ethics has not yet been addressed. With regard to operating in an ethical way, Recital (24) refers to adhering to ethical principles, such as the European ethical principles for digital health adopted by the eHealth Network on 26 January 2022.[87] These were mapped with CEN-ISO/TS 82304-2 in Table 3:

Table 3 Mapping European ethical principles with CEN-ISO/TS 82304-2

Mapping ethical principles	
European principles	**Related CEN-ISO/TS 82304-2 requirements**

[87] https://sante.gouv.fr/IMG/pdf/220131_european_ethical_principles_for_digital_health_fr_eng.pdf

1. Digital Health complements and optimizes face-to-face healthcare	**5.2.4.4** (aware of need for support health professional), **5.2.5.1** (societal benefit), **5.2.5.1.1** (evidence includes peer reviewed research with this app).
2. Individuals are informed about the benefits and limits of Digital Health	The CEN-ISO/TS 82304-2 label details Platform icons for the platforms an app supports (Android, iOS, other), Benefit of the app (**5.2.1.4**, **5.2.4.1**), For use by (**5.2.1.1**, **5.2.1.3**) and Do not use if (**5.2.1.2**). The full label also provides A-E scores. The health app quality report, the detailed version of the label, provides more detail.
3. Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them	**5.3.2.5** (adequate product information), **5.3.2.6** (instructions for use), **5.3.2.1** (app design based on an explicit understanding of users, tasks and environment), **5.3.2.2** (intended users involved throughout design and development app)**, 5.3.2.3** (design app driven and refined by user-centred evaluation), **5.3.1.2** (app appropriate given intended user diversity)
4. When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias	**5.2.4.2** (made aware of (health) interventions to achieve the health benefit), **5.2.3.1** (ethical challenges app assessed with intended users and health professionals), **5.2.3.2** (ethics advisory board)
5. Individuals are actively involved in shaping the European and national frameworks of Digital Health and data	The European Patients' Forum was a consortium partner in Label2Enable, many Label2Enable studies included persons with low health literacy, the CEN-ISO/TS 82304-2 assessment framework was informed by a Delphi study involving 83 experts from 8 stakeholder groups, including patients/citizens/carers.[21]
6. Individuals can easily and reliably retrieve their health data in a commonly used format	**5.5.2.1** (APIs), **5.5.2.2** (terminologies), **5.5.2.4** (obtain health data by data export to another platform)
7. Individuals can easily get information on how their health data have been or may be accessed and for which purpose	**5.4.1.1.4** (privacy statement), **5.4.1.1.4.1** (privacy statement starts with an accessible overview), **5.4.1.1.6** (opt-in default setting for sharing personal data with third parties)
8. Individuals can easily and reliably grant access to their health data and exercise their rights,	**5.5.2.4** (obtain health data by data export to another platform), **5.4.1.1.4** (privacy statement)

including objection when applicable	
9. Digital Health services are accessible by all, including by people with disabilities or low levels of literacy	**5.3.1.1 (**app WCAG 2.1 AA or AAA compliant), **5.3.1.1.1** (WCAG 2.1 AA compliant measures so all intended users can perceive app), **5.3.1.1.2** (WCAG 2.1 AA compliant measures so all intended users can operate app, **5.3.1.1.3** (WCAG 2.1 AA compliant measures so all intended users can understand app), **5.3.1.2** (app appropriate given intended user diversity)
10. Digital Health services are intuitive and easy to use	**5.3.2.1** (app design based on explicit understanding users, tasks and environment), **5.3.2.2** (intended users involved throughout design and development app), **5.3.2.3** (design app driven and refined by user-centred evaluation), **5.3.2.4** (measures to avoid use error and foreseeable misuse app), **5.3.2.8** (relevant data usability app systematically gathered for regular improvements)
11. Individuals have access to Digital Health training	**5.3.2.6** (instructions for use)
12. Digital Health services include support through human communication when needed	**5.3.2.7** (resources to adequately help users who experience problems with app)
13. Environmental impacts of Digital Health are identified and measured	**5.2.3.1** (ethical challenges app assessed with intended users and health professionals)
14. Digital Health services are developed in compliance with eco-design best practices	**5.2.3.1** (ethical challenges app assessed with intended users and health professionals)
15. Re-use and recycling of Digital Health equipment is ensured	**5.2.3.1** (ethical challenges app assessed with intended users and health professionals)
16. Digital Health stakeholders are committed to reducing their ecological footprint	

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5. MANUFACTURER GUIDELINES

This chapter provides the manufacturer guidelines based on the analysis of the EHDS and ethics in Chapter 4, feedback from Member States on a previous draft of D8.3, responses to our questions from project officers, and learnings from the survey (**Appendix I**) to the extent applicable. This includes a version embedded in the Label2Enable handbook for CEN-ISO/TS 82304-2 to the extent that these needed changes as a result of the alignment (Paragraph 5.3), a short version (Paragraph 5.4), and for consideration a potential solution to benefit from the evidence acquired for the CEN-ISO/TS 82304-2 label in the Label2Enable project (Paragraph 5.2). These interpretations and draft guidelines will be subject to multi-stakeholder feedback in September/October 2025.

5.1 CEN-ISO/TS 82304-2 found capable

Our analysis of the EHDS, ethics and CEN-ISO/TS 82304-2 revealed CEN-ISO/TS 82304-2 is more rigorous in methodology (third-party assessment) and scope than (solely) the requirements from EHDS Articles 47 to 49 and the narrow interpretation of *mutatis mutandis* for Annex II, potentially in part as a side effect of the introduction of the harmonised components and the limitation of the requirements in Annex II to largely that scope. The relevancy of CEN-ISO/TS 82304-2 requirements relies heavily on the interpretation of interoperability, safety and security features [Annex II Section 1.3] and reliable and secure [Annex II Section 1.4]. We interpreted as detailed above interoperability, safety and security features [Annex II Section 1.3], based on the Task 8.3 assignment to consider EU regulations in place and the D5.1 interpretation, to equal compliance to these regulations to the extent these requirements concerned interoperability, safety and security. Our interpretation of reliable and secure [Annex II Section 1.4] was based on a mapping with D5.1, see **Appendix II**.

This rigour also meant that the Label2Enable handbook for CEN-ISO/TS 82304-2 (Label2Enable D2.2) was found capable of supporting the development of wellness applications according to interoperability and security requirements under ISO standards. For all EHDS requirements a matching CEN-ISO/TS 82304-2 requirement was found. This match focused on the topic addressed, not necessarily on how the CEN-ISO/TS 82304-2 quality requirement question was phrased. The parts of the handbook that were adapted as a result of this work are displayed below, and aim to support:

- wellness app manufacturers in producing high-quality wellness applications that comply with the EHDS requirements if they claim interoperability with an EHR system [Xt-EHR D8.3],
- market surveillance authorities in checking compliance with the EHDS [Article 47(7)],
- Member State authorities in their potential (initial) considerations on adopting CEN-ISO/TS 82304-2, referring to their freedom to regulate other aspects of the use of wellness applications [Recital 50], combined with the aims to improve the functioning of the internal market [Recital 1], reduce

fragmentation, and increase inclusiveness [Recital 7], and achieve the multi-stakeholder trust that supports the intended useful use of patient-provided data [Article 5],
- CEN-ISO/TS 82304-2 conformity assessment bodies in (voluntary) quality assessments of wellness applications that (also) claim interoperability with EHR systems.

If the guidelines are to focus on EHDS compliance only, only the relevant, updated or added (displayed in **bold green**) notes in the "Additional guidance and evidence" of the handbook are to be extracted. This is displayed in Paragraph 5.4. The relevant, updated or added additional evidence and assessment sub-questions (displayed in **bold blue**) are not intended for use by manufacturers. Instead, these may support market surveillance authorities when checking compliance and are intended for use by CEN-ISO/TS 82304-2 conformity assessment bodies.

Summarizing, of the 67 score-impacting CEN-ISO/TS 82304-2 requirements, see Figure 8, 6 quality requirements were considered applicable given Articles 47 to 49 and our interpretation of *mutatis mutandis* [Annex II]. Of those, 4 could already get and have acquired changes to achieve alignment with the EHDS, for the remaining 2 guidance with regard to the EEHRxF and related granularity is needed. Applicability of another 27 CEN-ISO/TS 82304-2 requirements depend on the width of the interpretation of Annex II Sections 1.3 ("interoperability, safety and security features to uphold the rights of natural persons") and 1.4 ("interoperability and compatibility are reliable and secure"), another 19 would apply in case of alignment with the European ethics guidelines, and yet another 10 could potentially be applicable if Annex II Sections 1.1 and 1.2 would be interpreted as applicable for wellness applications. This applicability could further expand based on the interpretation of Annex II within D5.1 (see **Appendix II**).

See Figure 8 for an overview of the 67 CEN-ISO/TS 82304-2 quality requirements, displayed within the 4 CEN-ISO/TS 82304-2 quality aspects (Healthy and safe, etc.) and 11 sub-aspects (Health requirements, etc.) and their applicability for EHDS compliance. Applicability was colour-coded in the following sequence:
dark green: applicable, given EHDS Articles 47 to 49 and our (narrow) interpretation of Annex II,
olive green: potentially applicable given interpretation interoperability, security and safety features as compliant with EU level interoperability, security and safety legislation [Annex II Section 1.3] and reliable and secure as addressed in interpretation D5.1 for the related Section [Annex II Section 1.4],
light green: potentially applicable given Annex II Section 1.4 but not addressed in D5.1 for the related Section,
bright blue: potentially applicable given mapping with the European ethical principles,
light blue: potentially applicable if Annex II Sections 1.1 and 1.2 would be considered to apply.

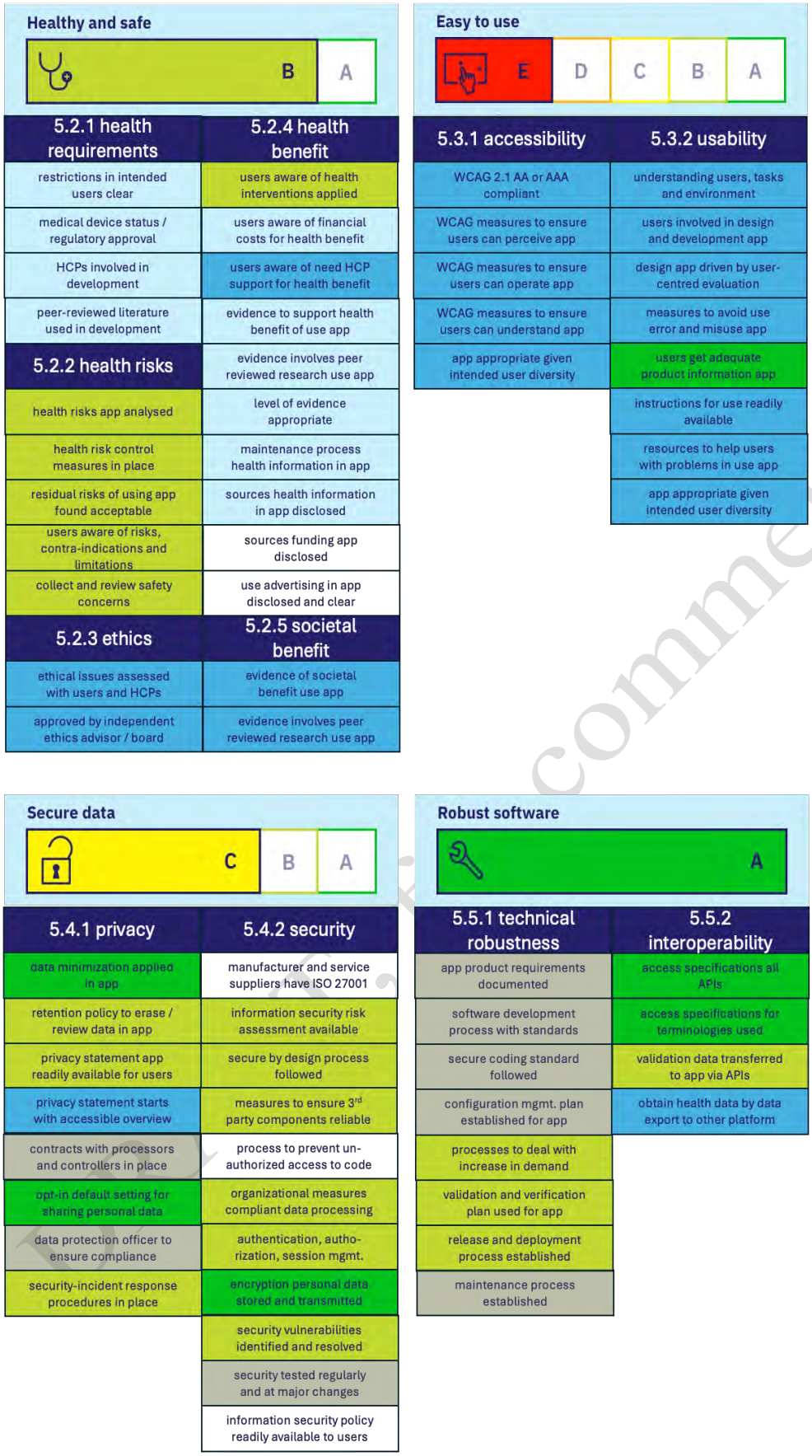

Figure 8 Overview potential applicability CEN-ISO/TS 82304-2 requirements for EHDS compliance

5.2 The potential of an abbreviated CEN-ISO/TS 82304-2 label and Recital 50

Article 47(1) details that a wellness application shall be accompanied by a label, clearly indicating its compliance with the common specifications referred to in Article 36 and essential requirements laid down in Annex II. The label shall be issued by the manufacturer of the wellness application. The Label2Enable handbook for assessment with CEN-ISO/TS 82304-2 is intended for use by certified conformity assessment bodies, to create the multi-stakeholder trust that is currently lacking. According to the ISO 17000 series compliant certification scheme for CEN-ISO/TS 82304-2 created by the Label2Enable project a certification body issues the label. Certification always involves third-party assessment, while labelling may or may not, put differently "all certifications are a label, but not all labels are certifications".[88] Certification or third-party conformity assessment provides assurance that a product, process, service or system meets specific requirements, stated in standards, regulations, contracts, programmes or other normative documents[89], while labels provide consumers with information about that product, process, service or system to help them make informed decisions[90]. Recital 49 states that a mandatory certification scheme for (*all)* wellness applications would not be proportionate, given the large number of wellness applications and the limited relevance for healthcare purposes of the data produced by many of them. Instead, a mandatory labelling scheme for wellness applications *for which interoperability is claimed* should be established as an appropriate mechanism for providing transparency for the users of wellness applications, thereby supporting users in their choice of appropriate wellness applications with high standards of *interoperability and security*.

The Commission shall, by means of implementing acts, determine the format and content of the label for wellness applications [Article 47(3)]. As the EHDS wellness application label would be self-declaration, confusion with the CEN-ISO/TS 82304-2 label (third-party assessment) would have to be avoided to ensure trust in the CEN-ISO/TS 82304-2 label and maintain its effect on multi-stakeholder behaviour. At the same time, it would be advantageous if the EHDS label could benefit from the many studies Label2Enable engaged in and the mounting evidence of the CEN-ISO/TS 82304-2 label, following findings from international research into energy information labels which demonstrated that label design by committee or policy and technical stakeholders rarely matches the needs of consumers as found in market research.[91] The CEN-ISO/TS 82304-2 label was built on the very well understood and extensively used designs of the EU energy label and Nutri-Score. The Label2Enable studies among other showed:

- 86% of consumers (n=1236) think the government should review and rate health apps, or commission an appropriate organisation to do so on their behalf, to help consumers choose a health app (Label2Enable D4.1),

[88] http://www.inquiriesjournal.com/articles/965/important-distinctions-between-labels-and-certifications-and-why-they-matter
[89] https://www.iso.org/conformity-assessment.html
[90] https://www.eca.europa.eu/en/publications?ref=SR-2024-23
[91] https://www.clasp.ngo/wp-content/uploads/2021/01/2005-05_MultiCountryComparativeEvaluationOfLabelingResearch.pdf

- healthcare professionals (n=116) are more willing to recommend health apps with a CEN-ISO/TS 82304-2 label[92] (Label2Enable D5.2.1),
- consumers (n=1106) including many with low health literacy are more willing to download health apps with a CEN-ISO/TS 82304-2 label in comparison to app store star ratings (Label2Enable D5.3),
- also persons with low health literacy (n=789) have a more adequate understanding of health app quality with the CEN-ISO/TS 82304-2 label and a video that explains the label. Who is behind the label (authority or manufacturer) was of major importance to their trust (Label2Enable D4.3),
- small changes to the CEN-ISO/TS 82304-2 label design, based on think-aloud testing in 4 corners of Europe (France, Hungary, Italy, Sweden) with a focus on persons with low health literacy (n=22), further increase understandability of the label (Label2Enable D4.2).

The CEN-ISO/TS 82304-2 label has already been translated in 26 languages[93] [Article 47(4)] including all official EU languages with the exception of Irish and Maltese, as English is also an official language in both Ireland and Malta and widely spoken in both countries. The explanatory videos that were co-created with persons with low health literacy (of importance in Recital 7) and tested positively in the Label2Enable project are subtitled in the same 26 languages.[94] The CEN-ISO/TS 82304-2 label could be expanded to include EHDS compliance for specific categories of personal electronic health data [Article 47(2a]), and already includes a reference to common specifications at the bottom [Article 47(2b)]. A date when the app was last checked is included, a validity period [Article 47(2c)] not, as apps tend to frequently issue new versions. These may include significant changes that may affect compliance, as also flagged in D5.1. Also, the lifetime of a health and wellness app can be considerably less than the proposed maximum 3 years.[95]

We distinguish two scenarios which are ideally combined to benefit from the existing CEN-ISO/TS 82304-2 label evidence while not eroding trust in the ICEN-SO/TS 82304-2 label that may be of interest for the EHDS wellness application label. One scenario is related to the EU level implementing legislation and the other related to potential Member State level legislation or other compelling guidance:

1. EU level implementing legislation: The EHDS label is self-declaration of a limited set of requirements reflecting the guidelines in Paragraph 5.4. These all need to be met, perhaps to be confirmed with a tick in the box at the potential label generator or EU database for registration of EHR systems and wellness applications, a further scoring mechanism such as in CEN-ISO/TS 82304-2 Annex B is not needed. For this label an abbreviated version of the CEN-ISO/TS 82304-2 label could be applied in which categories for which interoperability [Article 47(2a)] has been claimed are addressed. See Figure 9 at the right side for a draft. This abbreviated version could incentivize manufacturers to

[92] https://journals.sagepub.com/doi/full/10.1177/13591053241258205

[93] https://label2enable.eu/results - initial label translations

[94] https://vimeo.com/showcase/11257693

[95] https://www.iqvia.com/newsroom/2021/07/consumer-health-apps-and-digital-health-tools-proliferate-improving-quality-and-health-outcomes-for

(voluntarily) pursue the full CEN-ISO/TS 82304-2 assessment that drives multi-stakeholder trust and may thus also ultimately affect health professionals' considerations to use patient-provided wellness app data as intended in Article 5, as well as support cross-border scaling, in part depending on decision-making on a Member State level (scenario 2). This voluntary assessment would be third-party certification, would use the CEN-ISO/TS 82304-2 Annex B scoring mechanism and add the health app quality scores for "Healthy and safe", "Easy to use", "Secure data", "Robust build" and the overall health app quality score to the label.

2. National level implementing legislation or other compelling guidance: As (1) Member States may regulate other aspects of the use of wellness applications [Recital 50], (2) several authorities and other stakeholders expressed (severe) concerns in the first consultation round with respect to the label being self-declared, or advocated for certification, exemplified by frontrunner Germany's certification processes for DiGA (medical devices) and DiPA (not necessarily medical devices) being quite similar, similar concerns were raised for not addressing medical assessment of content and purpose, and (3) responses from the survey and consultation reveal other aspects such as accessibility (WCAG), usability and ISO 27001 are considered of importance on a national level, Member States may specify or otherwise promote a full CEN-ISO/TS 82304-2 (third-party certification) label to which categories for which interoperability has been claimed [Article 47(2a)] are added. See Figure 9 at the left side for a draft. Expert support would be recommended to support decision-making on Member State level to consider using CEN-ISO/TS 82304-2 with a minimum set of context-specific (e.g. Member State or region specific) requirements on top to avoid fragmentation [Recital 7], combined (for both scenarios) with a further exploration of the potential of automated assessments to support self-declaration, third-party assessment, market surveillance, and efficient compliance, as well as HTA, given usefulness of automated assessment for both health and wellness apps.

Both draft labels displayed in Figure 9 were built on the draft updated design of the CEN-ISO/TS 82304-2 label that incorporates draft findings from think-aloud testing with in total 22 persons from France, Hungary, Italy and Sweden, a significant number of whom had low health literacy (Label2Enable D4.2). Draft changes include:

- at the top the EU flag and at the bottom the third party who performed the assessment to add trust,
- simplification of Benefit of the app / For use by / Do not use if, and
- Robust software instead of Robust build as a health app quality aspect and score.

The dummy categories of health data in the labels in Figure 9 for which interoperability was claimed have been described in terms understandable to wellness application users (*"User can insert in their own electronic health record: Sleep data, mood data"*).

These scenarios take into account findings in Norway in which self-assessment of a selection of CEN-ISO/TS 82304-2 requirements was applied in a pilot with 5 apps. The self-assessments (at a time when the

Label2Enable handbook for CEN-ISO/TS 82304-2 was not yet available) resulted in labels indicating maximum attainable quality (largely dark green in the Label2Enable scheme), whereas the Label2Enable pilot, which was conducted with 24 manufacturers and 5 conformity assessment bodies with the full CEN-ISO/TS 82304-2 handbook, did not result in any full dark green label (yet). Of note, none of these applications had had the luxury of being able to develop their application with CEN-ISO/TS 82304-2, given its relatively recent publication.

Full updated CEN-ISO/TS 82304-2 label (third-party assessment, voluntary, Member State)

Abbreviated updated CEN-ISO/TS 82304-2 label (for potential use EHDS label, self-declaration)

Figure 9 Proposed full updated label (voluntary/ Member State adoption) and abbreviated version (for potential use EHDS label)

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1836 **5.3 The manufacturer guidelines embedded in the Label2Enable handbook ("under ISO standards")**

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CEN-ISO/TS 82304-2	**Requirement**	**5.5.2.1 Are potential customers and users of the health app able to access the specifications and implementation guides for all the APIs?**
	Notes	RESPONSE OPTIONS: Yes / No / Not applicable If the health app exchanges unstructured data, commonly accepted formats, e.g. Clinical Document Architecture (CDA) and Portable Document Format (PDF), should be used [32]. There can be additional costs to access the relevant standards. While such technical details are not relevant to all users, they can for example be used for assessing compatibility of the health app with other systems in a health service. NOTE 1 'APIs' are Application Programming Interfaces to for example external devices, websites, apps or other software. NOTE 2 Examples of external devices include scales and blood pressure devices not native to the app. NOTE 3 Examples of other software include Electronic Health Records, Personal Health Records and web services. NOTE 4 Examples of suitable specifications for external devices are published by Personal Connected Health Alliance,[50] Bluetooth Low Energy (BLE), and ANT Wireless (ANT+)[35]. NOTE 5 Suitable standards for interfaces to health software are published by IEC, ISO, CEN, IEEETM, HL7®6), IHE®6), DICOM®6) and GS1®6). NOTE 6 'Not applicable' indicates the health app does not have APIs.
	Evidence	Regular access to specification and implementation guides.
Handbook	**Additional guidance and evidence**	Please provide additionally: 1. for the health app quality report, list of all APIs with interoperability standards used and link to specification / implementation guidelines

		2. also for the health app quality report, if the app claims interoperability with an electronic health record system, for which categories of electronic health data **3. if the app claims interoperability with an electronic health record system, confirmation that the European electronic health record exchange format (EEHRxF) is supported, and evidence of such** 4. if available, data flow diagram **NOTE 1 'EHR system' (electronic health record system) means any system whereby the software, or a combination of the hardware and the software of that system, allows personal electronic health data that belong to the priority categories of personal electronic health data established under the European Health Data Space (EHDS) Regulation to be stored, intermediated, exported, imported, converted, edited or viewed, and intended by the manufacturer to be used by healthcare providers when providing patient care or by patients when accessing their electronic health data. A health and wellness app is not an EHR system.** NOTE 2 APIs for both import and export should be included. **NOTE 3 According to Article 5 of the European Health Data Space regulation (EHDS), users have a right to insert information in their own electronic health record. This can include personal electronic health data from wellness applications (and medical devices) for which interoperability with an EHR system has been claimed by the manufacturer. See for a flowchart if an app is a wellness application [URL]. An EHR system shall accept patient-provided personal electronic health data if the European electronic health record exchange format (EEHRxF) is used. See for more information on the EEHRxF [URL] and testing tools [URL]. If interoperability is claimed for specified categories of electronic health data, a manufacturer of a wellness application shall ensure compliance with the common specifications of Article 36 and essential requirements of Annex II and issue a label (Article 47(1)) as described in the EHDS implementing acts [URL]. See for a label generator [URL]. This label shall be available at the point of sale and accompany each individual unit of the wellness application placed on the market or put into service free of charge. If the wellness application is part of or embedded in a device, the label shall be shown in the application itself or placed on the device, if the wellness application consists only of software the (digital) label shall be shown in the application itself (Article 47(6)). Additionally, a manufacturer shall register the wellness application into the EU database for registration of EHR systems and wellness applications (Article 49(4)) before placing the application on the market or putting it into service. If the application is a medical device, *in vitro* diagnostic medical device or high-risk AI system claiming interoperability, the data entered in the databases established in the MDR and AI Act shall forward the relevant data to the EU database for registration of EHR systems and wellness applications. For access to the database click [URL]. See 5.3.2.5 and 5.4.1.1.6 for related requirements. An update to 5.5.1.1 (product requirements) as to the interoperability supports the manufacturer in maintaining compliance with the EHDS and validating and verifying compliance (5.5.1.6) in case of updates of the application. *[This information could be abbreviated if it refers to the short version of the guidelines in***

		Chapter 5.4 and will be updated if applicable after the consultation in September/October 2025.]
	Sub-questions	**Does the evidence supplied, a check in the app, at the point of sale and in the EU database for registration of EHR systems and wellness applications confirm:** **1. if the app claims interoperability with an electronic health record system, it supports the European electronic health record exchange format?** 2. a list of (all) APIs implemented within the app? 3. the specifications and implementation guides are accessible for all APIs without having to contact the manufacturer? **4. If the app is a wellness application according to the EHDS that claims interoperability with an electronic health record system, an appropriate label accompanies the app free of charge?** **5. If the app claims interoperability with an electronic health record system, registration in the database for registration of EHR systems and wellness applications?**
	Pass / fail	To pass, all sub-questions need to be answered yes.
Pass / fail 2025		
Initial analysis potential for automated assessment		To further check: https://www.ihe-europe.net/testing-IHE/gazelle https://interoplab.nl/in-de-praktijk/
Likely mandatory within EU (EU level legislation)		EHDS (if a wellness application for which interoperability with an EHR system was claimed)

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CEN-ISO/TS 82304-2	**Requirement**	**5.3.2.5 Are potential customers and users provided with adequate product information about the health app?**
	Notes	RESPONSE OPTIONS: Yes / No Product information shall be provided to potential customers and users, to help them decide whether the app is suitable. The app descriptions: — shall include the main functionality, the intended use, the intended users and the potential use of the user's personal data by the app; — shall accurately depict screen shots of the current version of the health app;

		— shall clearly note the payment amount for the app, if any, if applicable, according to digital marketplace rules; — should clearly state the human languages the health app supports, referred to in 5.1.1.4; — should communicate information about the app manufacturer, referred to in 5.1.2.1, and mechanisms to communicate with the app manufacturer; — should show the date of the last update to the health app and describe the changes from the previous release, for instance revisions due to new scientific evidence; — should declare the degree of admission of liability (app manufacturer acceptance or disclaimer of responsibility regarding the selection and use of the app's content); - can identify the health professionals and those who worked on the app and/or at least the professional organization that made, reviewed, endorsed, or sponsored the app; — can include data related to app reliability and validity; — should provide information about accessibility characteristics; — shall give attribution to any open source code library or code under copyright used to develop the app.
	Evidence	Link to the primary publicly available source of information about the health app for potential customers and users, for example a website or entry in a digital marketplace.
Handbook	**Additional guidance and evidence**	Please provide additionally: 1. for the health app quality report, a link to the product information of the app, for instance on the manufacturer website, which includes disclaimers and terms and conditions. **NOTE According to Article 5 of the European Health Data Space regulation (EHDS), users have a right to insert information in their own electronic health record. This can include personal electronic health data from wellness applications. See for a flowchart if an app is a wellness application [URL]. Article 48(1) of the EHDS requires manufacturers of wellness applications that claim interoperability with an EHR system for specific categories of personal electronic health data to duly inform users of this interoperability and the effects of such interoperability. Duly inform is considered a narrative text that is readily available and explains understandably and brief (1) the data categories that can be shared by this particular app, (2) types of EHR systems it can be shared with, (3) how these data could be useful if inserted in their own electronic health record and what use could be made of it, referring to reliable sources, if available, to support the claim of usefulness and raising awareness to any risks, contra-indications and limitations of use, if available referring to relevant European medical society guidelines, (4) how the user is able to choose which categories of data from the wellness application are to be inserted**

		in the EHR and the circumstances for the sharing or transmission, and that actual sharing of data is only possible after the user has given consent and that the interoperability shall be limited exclusively to those purposes (Article 48(2)), (5) how the interoperability works, e.g. privacy aspects of the interoperability, that these data will be labelled in the EHR as patient-provided data (Article 5, that health professionals who are authorised to access their EHR can see it there to take into consideration, and that an anonymised or pseudonymised version of these data may also be made available for purposes that would benefit society, such as research, development and policy. See for an example and template of such a message [URL]. *[This information could be abbreviated if it refers to the short version of the guidelines in Chapter 5.4 and will be updated if applicable after the consultation in September/October 2025.]*
	Sub-questions	**Does the evidence supplied include:** 1. if not a web app, current version of the app, version of the operating systems it supports (5.1.1.1), update date and changes compared to the previous version? 2. current screenshots of the app? 3. languages? (5.1.1.4) 4. manufacturer and contact information? (5.1.2.1) 5. intended users? (5.2.1.1-5.2.1.3) 6. intended use(s) of the app? (5.2.1.4) including details on offline use and devices supported 7. medical device status? (5.2.1.5) 8. if health professionals and/or organizations were involved in the development (5.2.1.6), names of these health professionals and/or organizations? 9. if scientific literature was used in the development (5.2.1.7), the scientific literature used? 10. if applicable, a disclaimer? (5.2.2.5) 11. the main functionality of the app? (5.2.4.1) 12. if the app has a health benefit, (health) intervention(s) used? (5.2.4.2) 13. payment information for the app including related services and products or indication the app is free of charge? (5.2.4.3) 14. if the app needs professional support for health benefit (5.2.4.4), relevant details? 15. if the app claims health benefit(s) (5.2.4.5), claim? 16. if maintenance process of app content (5.2.4.6), review intervals? 17. if other sources of funding (5.2.4.7), relevant details? 18. if use of advertising (5.2.4.8), relevant details? 19. accessibility features? (5.3.1)

		20. information about the potential use of the user's personal data by the app? (5.4.1.1.4) 21. attribution to any open-source code library, or code under copyright, used to develop the app or a statement none of those are used? (5.5.1) (e.g. open source/third-party software in about screen or under copyright section) 22. the terms and conditions of the app? **23. If the app is a wellness application according to the EHDS that claims interoperability with an electronic health record system, a narrative text that duly informs users as detailed in the related note?**
	Pass / fail	To pass, all sub-questions need to be answered yes, or if the condition is not met, answered N/A.
Pass / fail 2025		
Initial analysis potential for automated assessment		E.g., https://42matters.com/app-market-explorer for native apps.
Likely mandatory within EU (EU level legislation)		MDR + EHDS (if a wellness application for which interoperability with an EHR system was claimed)

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CEN-ISO/TS 82304-2	Requirement	**5.4.1.1.6 Is opt-in the default setting for sharing PII with third parties?**
	Notes	CONDITION: 5.4.1.1 Yes RESPONSE OPTIONS: Yes / No / Not applicable Opt-in refers to requiring the PII subject's consent. The consent should be: — freely given; — specific regarding the purpose for processing; — unambiguous and explicit (adapted from ISO/IEC 27701:2019, 7.2.4). Before exporting data, the app user shall be asked for permission to transmit the data with an explanation of what data is being transmitted, and to which recipients for what purposes (e.g. to servers of the app supplier, for backups, for big data analysis). Permission is requested before the first potential transmission of data. Permission is re-requested the first time any additional data elements are sent to an external data source when permission had previously been extended for a smaller

		set of data. Permission is not requested at every transmission, if the scope of exported data remains unchanged [32]. This can include cookies and other tracking technologies used to share information with third parties, as well as sharing data with social networks. NOTE 'Not applicable' indicates no data is shared with third parties.
	Evidence	Screenshots of opt-in and sources of the screenshots, and cookie statement and cookie scan report
Handbook	Additional guidance and evidence	**Please provide additionally:** 1. evidence (e.g. screenshots) that users are required to provide separate opt-in for cookies and marketing **2. Once the European Health Data Space (EHDS) regulation is in force, for apps that claim interoperability with an EHR system, evidence (e.g. screenshots) that users are enabled to choose which categories of data to share or transmit and under which circumstances and the subsequent need to give consent** NOTE 1 'third party' means a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data (GDPR Article 4(10)). **NOTE 2 According to Article 5 of the European Health Data Space regulation (EHDS), users have a right to insert information in their own electronic health record. This can include personal electronic health data from wellness applications. See for a flowchart if an app is a wellness application [URL]. Article 48(2) of the EHDS requires manufacturers of wellness applications that claim interoperability with an EHR system for specific categories of personal electronic health data to enable the user to choose which categories of health data from the wellness application are to be inserted in the EHR system and the circumstances for sharing or transmitting those categories of data. Examples of circumstances could be periodically (e.g. every week) or if above or below a certain threshold. The actual sharing or transmitting is only possible after user consent, automatic sharing of all or part of the data without consent is not possible. Also, consent shall be limited exclusively to the purpose of inserting data in their own EHR. Manufacturers need to use the European electronic health record exchange format to share or transmit these data to the EHR system.** ***[This information could be abbreviated if it refers to the short version of the guidelines in Chapter 5.4 and will be updated if applicable after the consultation in September/October 2025.]***

		NOTE 3 Requiring the user to opt-out or no option at all would indicate response option 'No' for this quality requirement. Agreeing to a privacy statement is not sufficient.
	Sub-questions	**Does the evidence supplied confirm:** 1. before the first related data export, as a default setting, the data subject is asked for permission (cookies and marketing) to transmit the data with an explanation of what data is being transmitted to which third-party recipients for what purposes? **2. if the app is a wellness application according to the EHDS, that claims interoperability with an electronic health record system, the user is enabled to choose which categories of personal electronic health data for which interoperability has been claimed are to be inserted in their own EHR and the circumstances for the sharing or transmission of those categories of data?** **3. if the app is a wellness application according to the EHDS, that claims interoperability with an electronic health record system, before the first related data export, as a default setting, the data subject is asked for consent (EHDS) to transmit the data with an explanation of what data is being transmitted to which third-party recipients for what purposes?**
	Pass / fail	To pass, the sub-question needs to be answered yes.
Pass / fail 2025		
Potential for automated assessment		
Likely mandatory within EU (EU level legislation)		GDPR + EHDS (if a wellness application for which interoperability with an EHR system was claimed)

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CEN-ISO/TS 82304-2	Requirement	**5.4.1.1.2 Is data minimization applied in the health app?**
	Notes	CONDITION: 5.4.1.1 Yes RESPONSE OPTIONS: Yes / No The app manufacturer should identify how the specific PII and amount of PII collected and processed is limited relative to the identified purposes (ISO/IEC 27701:2019, 7.4.4). Privacy by design and privacy by default contribute to data minimization. Privacy by design ensures that processes and systems are designed such that the collection and processing (including use, disclosure, retention, transmission and disposal) are limited

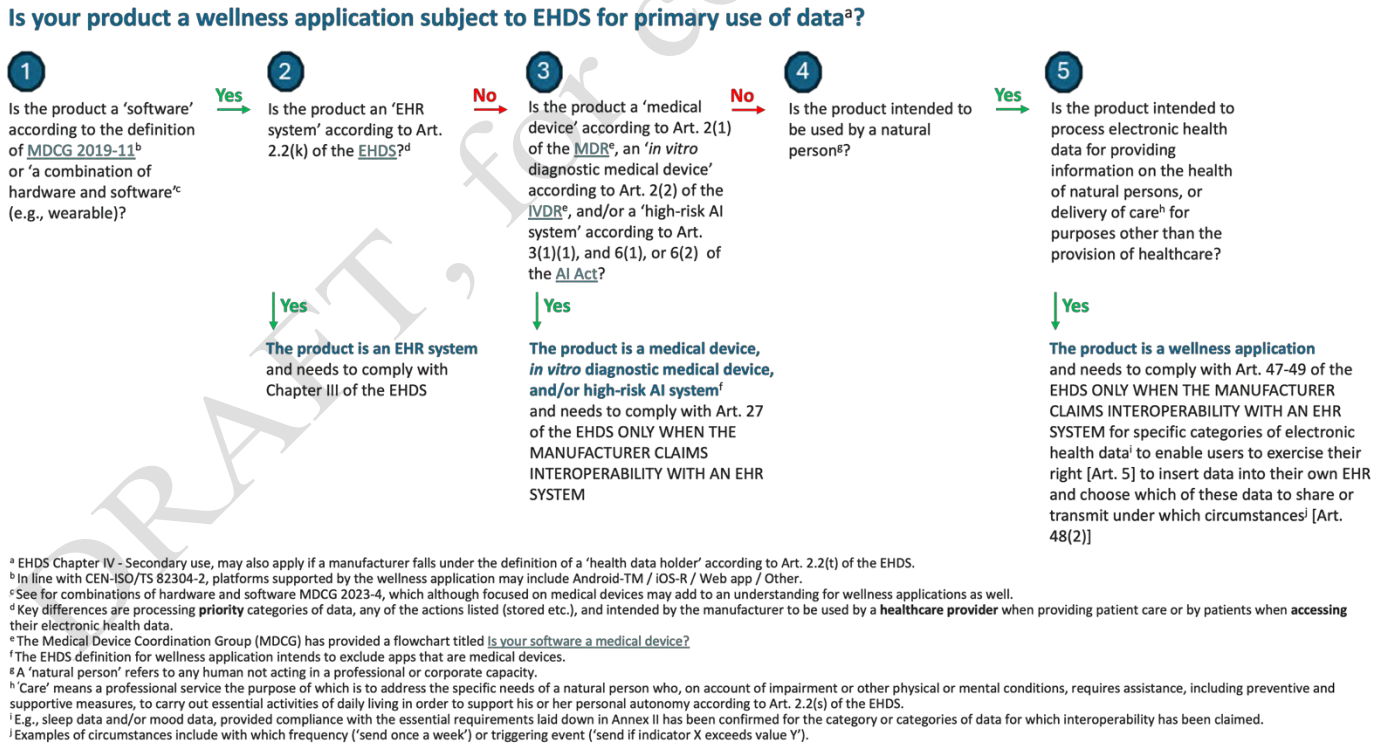
		to what is necessary for the identified purpose. Privacy by default implies that, where any optionality in the collection and processing of PII exists, each option should be disabled by default and only enabled by explicit choice of the data subject (adapted from ISO/IEC 27701:2019, 7.4). Data minimization shall include ensuring that: — the app reduces data granularity and anonymizes the data on the device instead of remotely, for instance stripping image metadata; — for purposes of establishing an account, the minimum necessary amount of a user's PII is collected (e.g. the information is necessary to authenticate the user, provide user support, or affect the app logic; — only platform functionality and data sources essential to perform specific functions of the app are used. This includes, but is not limited to, the use of location, services, camera, microphone, accelerometer and other sensors, contact lists, calendars; — the app stores the device number or IP addresses transmitted during use only to the degree needed to fulfil the application's purpose. NOTE Data minimization is achieved if PII is only processed where it isn't reasonably feasible to carry out the processing in another manner, and anonymous data is used where possible. EXAMPLE The use of de-identification and limiting the amount of PII that is collected indirectly, for instance through web logs, system logs, etc (ISO/IEC 27701:2019, 7.4.1 and 7.4.4).
	Evidence	Overview of PII processed and purpose e.g. from privacy statement
Handbook	Additional guidance and evidence	Please provide additionally: 1. data minimization policy that demonstrates that appropriate data minimization measures have been taken, considering among other pseudonymization including, if pseudonymisation is a suitable measure, a rationale for the stage at which it is applied, and, if the device number or IP address is stored, a rationale related to the intended use of the health app. 2. if applicable, Data Protection Impact Assessment (DPIA), which includes as per GDPR Article 35 an assessment of the necessity and proportionality of the processing operations in relation to the purposes.

		3. if available, data flow diagram specifying what data is collected from where / whom, what the manufacturer / app does with it, where it is stored and with whom it is shared. This would likely be part of a policy that demonstrates data minimization. NOTE 1 Guidance to create a data flow diagram: https://www.edps.europa.eu/sites/default/files/publication/ flowcharts_and_checklists_on_data_protection_brochure_en_1.pdf. NOTE 2 'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. (GDPR Article 4(5)) NOTE 3 This quality requirement relates to GDPR principle "data minimization", which requires that data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed. (GDPR Article 5.1(c)). **Sufficient granularity for the use of the European electronic health record exchange format (EEHRxF) as required for wellness applications and medical devices that claim interoperability with an electronic health record system as detailed in the European Health Data Space regulation can be considered necessary for the purpose and thus compliant with the GDPR principle data minimization.**
	Sub-questions	Does the evidence supplied, and a check of the health app confirm: 1. the personal data collected and processed (5.4.1.1 and 5.4.1.1.1) is limited to what is necessary for the intended purpose(s) (5.2.1.4) or otherwise justifiable activities? (e.g. to enable the health intervention, authenticate the user, provide user support or affect the app logic, includes platform functionalities such as the use of location, services, camera, microphone, accelerometer and other sensors, contact lists, calendars etc.) 2. the app reduces data granularity where possible? (e.g. birth year instead of birth date, country instead of city or postal code) 3. if data pseudonymization is a suitable measure, the data is pseudonymized as soon as possible? 4. if the app stores the device number or IP addresses transmitted during use, a solid rationale related to the intended use of the health app? 5. personal data is not used in the development or testing of the health app or other manufacturer-related uses?

	Pass / fail	To pass, all sub-questions need to be answered yes, or if the condition is not met, answered N/A.
Pass / fail 2025		
Potential for automated assessment		e.g. https://www.quokka.io/solutions/healthcare
Likely mandatory within EU (EU level legislation)		GDPR + EHDS (if a wellness application for which interoperability with an EHR system was claimed)

5.4 The manufacturer guidelines draft short version ("EHDS only")

According to Article 5 of the European Health Data Space regulation (EHDS), users have a right to insert information in their own electronic health record. This can include personal electronic health data from wellness applications (and medical devices) for which interoperability with an EHR system has been claimed by the manufacturer. This flowchart helps determine if a product is a wellness application according to the EHDS:



[a] EHDS Chapter IV - Secondary use, may also apply if a manufacturer falls under the definition of a 'health data holder' according to Art. 2.2(t) of the EHDS.
[b] In line with CEN-ISO/TS 82304-2, platforms supported by the wellness application may include Android-TM / iOS-R / Web app / Other.
[c] See for combinations of hardware and software MDCG 2023-4, which although focused on medical devices may add to an understanding for wellness applications as well.
[d] Key differences are processing **priority** categories of data, any of the actions listed (stored etc.), and intended by the manufacturer to be used by a **healthcare provider** when providing patient care or by patients when **accessing** their electronic health data.
[e] The Medical Device Coordination Group (MDCG) has provided a flowchart titled Is your software a medical device?
[f] The EHDS definition for wellness application intends to exclude apps that are medical devices.
[g] A 'natural person' refers to any human not acting in a professional or corporate capacity.
[h] 'Care' means a professional service the purpose of which is to address the specific needs of a natural person who, on account of impairment or other physical or mental conditions, requires assistance, including preventive and supportive measures, to carry out essential activities of daily living in order to support his or her personal autonomy according to Art. 2.2(s) of the EHDS.
[i] E.g., sleep data and/or mood data, provided compliance with the essential requirements laid down in Annex II has been confirmed for the category or categories of data for which interoperability has been claimed.
[j] Examples of circumstances include with which frequency ('send once a week') or triggering event ('send if indicator X exceeds value Y').

If a product is a wellness application and the manufacturer claims interoperability with an EHR system, the manufacturer has to meet the following requirements at different stages of the product lifecycle of the wellness application:

Design and develop application	Claim interoperability (pre-market)	Maintain compliance (post-market)
Meet applicable common specifications [Art. 36], essential requirements [Annex II] and wellness application specific requirements for interoperability [Art. 48(2)]	Label the app [Art. 47] Register the app [Art. 49] Duly inform users about the interoperability [Art. 48(1)]	Update product requirements with EHDS requirements Validate and verify at updates to maintain EHDS compliance

Design and develop application:

Article 47 specifies that where a manufacturer of a wellness application claims interoperability with an EHR system, the manufacturer shall ensure compliance with the common specifications of Article 36 and essential requirements of Annex II. *[To add, if applicable, information on requirements as to interoperability, security and safety features [Annex II 1.3], reliable and secure [Annex II 1.4] and ideally availability automated assessments is clear, and D5.1 recommendations, and the applicability of the European ethical principles (Paragraph 4.3) have been decided upon.]*

Article 48(2) of the EHDS requires manufacturers of wellness applications to enable the user to choose which categories of health data from the wellness application for which the manufacturer has claimed interoperability, are to be inserted in the EHR system and circumstances for sharing or transmitting those categories of data. See for guidance on which categories of electronic health data to claim interoperability for [URL]. Examples of circumstances could be periodically (e.g. every week) or if above or below a certain threshold. The actual sharing or transmitting is only possible after user consent, automatic sharing of all or part of the data without consent is not possible. Also, consent shall be limited exclusively to the purpose of inserting data in the user's own EHR. Manufacturers need to use the European electronic health record exchange format (EEHRxF) to share or transmit these data to the EHR system. This implies that capturing sufficient granular data to enable the use of the EEHRxF is considered a legitimate purpose from the perspective of data minimisation. See for more information on the EEHRxF granularity of data entry, and encryption needed [URL], and for testing tools [URL]. The gateway to the EHR system is the harmonised European interoperability software component for EHR systems.

Claim interoperability:

Article 47 specifies that where a manufacturer of a wellness application claims interoperability with an EHR system, the manufacturer shall ensure compliance with the common specifications of Article 36 and essential requirements of Annex II and issue a label [Article 47(1)] as described in the EHDS implementing acts [URL]. See for a label generator [URL]. This label shall include (a) the categories of electronic health data for which compliance with essential requirements laid down in EHDS Annex II has been confirmed, (b) a reference to common specifications to demonstrate compliance, and (c) the validity period of the label

[Article 47(2)]. If the wellness application is part of or embedded in a device, the label shall be shown in the application itself or placed on the device, if the wellness application consists only of software the (digital) label shall be shown in the application itself [Article 47(6)]. The manufacturer shall ensure the label accompanies each individual unit of the wellness application placed on the market or put into service free of charge [Article 47(8)] and supply the label to distributors so they can ensure the label is available at the point of sale [Article 47(9)].

Article 49 requires a manufacturer to register the wellness application into the EU database for registration of EHR systems and wellness applications [Article 49(4)] before placing the application on the market or putting it into service. If the application is a medical device, *in vitro* diagnostic medical device or high-risk AI system claiming interoperability, the data entered in the databases established in the MDR and AI Act shall forward the relevant data to the EU database for registration of EHR systems and wellness applications. For access to the database click [URL].

Article 48(1) details manufacturers of wellness applications that claim interoperability with an EHR system need to "duly inform" users of this interoperability and the effects of such interoperability [Article 48(1)]. Duly inform is considered a narrative text that is readily available and explains understandably and brief (1) the data categories that can be shared by this particular app, (2) types of EHR systems it can be shared with *[we expect that the consultation in September/October will clarify if this needs to be maintained or adjusted]*, (3) how these data could be useful if inserted in their own electronic health record and what use could be made of it, referring to reliable sources, if available, to support the claim of usefulness and raising awareness to any risks, contra-indications and limitations of use, if available referring to relevant European medical society guidelines, (4) how the user is able to choose which categories of data from the wellness application are to be inserted in the EHR and the circumstances for the sharing or transmission, (5) that actual sharing of data is only possible after the user has given consent and that the interoperability shall be limited exclusively to those purposes [Article 48(2)], (6) how the interoperability works, e.g. privacy aspects of the interoperability, that these data will be labelled in the EHR as patient-provided data [Article 5], that health professionals who are authorised to access their EHR can see these data there to take into consideration, and (7) that an anonymised or pseudonymised version of these data may also be made available for purposes that would benefit society, such as research, development and policy. See for an example and template of such a message [URL].

Maintain compliance:
Market surveillance authorities shall check compliance of wellness applications with the essential requirements laid down in Annex II [Article 47(7)]. An update to the product requirements of the wellness application as to this interoperability is recommended to ensure compliance with the EHDS is maintained, validated and verified in case of updates of the wellness application.

6. CONSIDERATIONS

This chapter lists overarching observations as well as considerations that we recommend the Commission and the Member States to take into account when preparing implementing legislation and support measures for the EHDS.

Suggestions:

1. EHR systems should label and perhaps handle patient-provided material differently depending on the source of the information
2. Encourage wellness app manufacturers to claim interoperability with EHR systems
3. Make Patient Summary 1.15 ready to receive data from wellness applications
4. Produce guidelines for wellness app manufacturers to assist their decision-making about:
   - data categories for which they want to claim interoperability, as well as
   - how to structure such data, and
   - what circumstances for the data transfer to offer to their users.
5. In border line cases, consider distinctive features of EHDS compliant wellness application as optional to be adopted by medical devices that fulfil the criteria of the wellness application definition
6. Make Digital Testing Environments and/or other testing tools available to wellness applications
7. Consider an abbreviated version of the CEN-ISO/TS 82304-2 label as the EHDS label
8. Improve the quality of the data by improving the quality of the wellness applications
9. Facilitate innovative new solutions by explaining how wellness applications may be able to benefit from EHR data when their user chooses to download data from the EHR system in EEHRxF and to upload it into the wellness application
10. Build on CEN-ISO/TS 82304-2 and Label2Enable deliverables as a basis for EHDS compliance

6.1 Encouraging health professionals, researchers and policy makers to consider patient-provided data

Incorporating wellness applications within the EHDS ecosystem is a welcomed feature of the EHDS Regulations, it is however yet to be seen how the interoperability requirements to support individuals in exercising their right to insert data into their EHR will translate into actual uptake, advancement in patient care and improving the internal market for EHDS compliant wellness applications. The key concern is not about whether manufacturers of wellness applications can meet the essential requirements as set out in the EHDS Regulation, but how to do it in a meaningful way so that all stakeholders benefit from the

inclusion of data from a wellness applications in an EHR as intended within the spirit of the EHDS and to harness the potential of this data.

Article 5 gives patients the right to insert information into their EHR, which will in turn be included in the patient summary as patient-provided data. As the right in Article 5 is very broad it allows the patient to upload any information they choose. If a patient exercises this right through the health data access services, it may only be a size / quality restriction of a file that limits what a patient may upload. No such restrictions have been detailed in the EHDS or D5.1 for wellness applications, even though such measures currently exist in practice to ensure useful quality data. According to feedback from a university medical center, data can currently only be uploaded if a patient and health professional have agreed on this. Instead of a natural person inserting data from their wellness application in their own EHR via the EHR interoperability software component, an order from the EHR system is sent to the patient app that ensures only the agreed data is accepted. That is data of a certain type, in a certain frequency, covering a certain period.

Not all information uploaded by a patient can be considered data to be included under the heading in Annex I 1.15. If the manufacturer wants to claim interoperability with an EHR system and enable the patient to insert data from a wellness application into their EHR on an automated basis by setting the circumstances of the data transfer, then such data must be in the EEHRxF format. Where automated integration is not chosen by the patient, there is of course nothing stopping a patient from downloading information from an application, or taking a screenshot, and manually adding such information into their EHR themselves (depending on how the data access service allows for such entry). In such a scenario it is irrelevant if the application manufacturer claimed interoperability with the EHDS or not. However, given that such information will not be interoperable data, it is questionable whether a health professional would trust it or a researcher or policy maker would choose to make use of it.

Suggestion 1: **EHR systems should label and perhaps handle patient-provided material differently depending on the source of the information.**

Although Article 5 requires patient-inserted information to be distinguishable from clinical data, we believe it is not sufficient to facilitate inclusion into the patient summary in a way that fits with the spirit of the EHDS.

What would be useful additionally is to tag information and store data in the EHR system based on its origin:

- information provided directly by the patient (upload pdf, create free text, etc…),
- data provided via an EHDS compliant product (essential requirements, EEHRxF, etc…), including e.g. timestamp, applying lessons learned in Germany with the MIO DiGA Toolkit as a FHIR Provenance resource,
- if considered relevant and feasible for cybersecurity reasons, a further distinction as to country where the manufacturer(s) and/or data storage are based,
- Within the group of EHDS compliant products, a further consideration may be given to distinguishing between who or what generated the data: health professionals and researchers may,

for example, want to know if information about food-intake is recorded by a user with an eating disorder or by their carer, a sensor, or originates from another source than the app (validated or non-validated import of data in the app). If a wellness application could log the source of data entry (as opposed to data access), it should be able to carry this information over to the EHR system.

Suggestion 2: **Encourage wellness app manufacturers to claim interoperability with EHR systems.**

Wellness app manufacturers should be addressed with a clear explanation about the benefits of claiming interoperability with EHR systems as well as the advantages of using standards that support the EEHRxF. By doing so, policymakers can create an environment where patients would favour EHDS-compliant products over sharing data produced by devices in alternative ways, whereby health professionals have no way to know whether to trust the data source. Having incentives for manufacturers towards interoperability and useful data would mirror the effective practices of the EU energy label which is part of a well-established toolbox of market transformation policy instruments that encourage manufacturers to produce more energy efficient products, sellers to stock them, and buyers to buy them.[96]

Suggestion 3: **Make Patient Summary 1.15 ready to receive data from wellness applications.**

Although 1.15 of the patient summaries is specified in Annex I of the EHDS as patient-provided data, the eHealth Network Guidelines on Patient Summary explains that this section is not intended for data injected directly by the patient. However, it adds that future revisions of the Patient Summary Guidelines might capture the need of such reported data. Given that no other logical place has been identified for EHDS-compliant wellness applications to send data to EHR systems in an EEHRxF, further work is needed to create specifications that would allow data to be inserted in a meaningful way so that it can be used for healthcare and secondary use purposes. Such specifications may include restrictions on data volume, data quality in line with the other suggestions, in particular 1, and 4.

Suggestion 4: **Produce guidelines for wellness app manufacturers to assist their decision-making about:**

- **data categories for which they want to claim interoperability, as well as**
- **how to structure such data, and**
- **what circumstances for the data transfer to offer to their users.**

Involving not just wellness app manufacturers but also patients, health professionals, medical societies and EHR vendors would be crucial to find a balance on what information should be considered as useful for patient care without it being too much or too little. If health professionals feel overwhelmed with information they do not trust and cannot interpret, there is a concern that data from wellness applications would be disregarded, which may have a knock-on effect on the demand and use of EHDS-compliant wellness applications and health apps in general.

[96] https://c2e2.unepccc.org/wp-content/uploads/sites/3/2016/04/2013-05-eu-energy-labelling-comprehension-study.pdf

6.2 Assessing products that claim interoperability from the users' perspective

Although the intention of the co-legislations was to make medical devices and wellness applications mutually exclusive, it would seem that there is still an overlap that should be addressed. Such overlap arises in medical devices that are intended to be used as consumer products but nevertheless have a certification as a medical device under MDR. An example would be the widely used fertility apps (see a real-world example the footnote[97]), which is used by a natural person, processes health data for providing information on the health of the natural person and is used for purposes other than the provision of healthcare. Such a fertility app would be a class IIb medical device based on the definition of medical devices in MDR which place *"devices for the control or support of conception"* under its umbrella but equally complies with all the requirements of a wellness application as defined in EHDS.

Despite the overlap between the definitions, the flowchart and guidelines presented above state that medical devices need to comply with EHDS as such based on Article 27. So mutual exclusivity is achieved not by the definition of the products but by sending medical devices and wellness apps into separate compliance routes. This could lead to confusion for patients / users, given that when they visit an app store, wellness applications will be labelled according to EHDS possibly with a distinctive, colourful label that is easily recognisable, while the application which is a medical device will show the CE label and Declaration of Conformity, which an average consumer might not associate as a source of information on interoperability features with EHDS. Also, an average consumer might not visit the EU database for EHR systems and wellness applications where compliant medical devices will also be displayed. An average consumer might just visit an app store, which according to the MDCG 2025-4 should separate medical device apps (medical device software apps) from health apps without a medical purpose. Staying with the example of a fertility app, it would be difficult to identify which one to use if a user is interested in asking for automated insertion from it onto their EHR.

A further example that would benefit from guidance is the medical device which can also be used as a consumer device, such as a blood glucose monitor which is provided as a medical device by a physician as part of insulin management for a person with diabetes, yet can also be used by a person with no clinical indication, who wishes to monitor blood glucose levels for dietary reasons. Although the device is the exact same, its intended use will define if in a particular circumstance it is a medical device or a wellness application.

Another issue to flag is data transfer: whereas wellness applications require consent and no automatic sharing of information is possible, the text of the EHDS implies that medical devices as part of the healthcare provision share data according to the applicable data protection rules of a healthcare setting. Coming back to the same example of the fertility app, there should be a duty to inform and consent mechanism similar to Article 48(1) and 48(2) in place to support inserting useful data into the EHR.

[97] https://ovyapp.com/en/blogs/news/die-ovy-app-wird-als-mdr-zertifiziertes-verhutungsmittel-zugelassen-wichtige-informationen-fur-ovy-app-nutzer-innen

Suggestion 5: **In border line cases, consider distinctive features of EHDS-compliant wellness applications as optional to be adopted by medical devices that fulfil the criteria of the wellness app definition.**

This way a medical device which is intended to be a consumer device "stays" a medical device and maintains compliance by EHDS and MDR (and AI Act if applicable), however, when facing customers, it may carry an EHDS interoperability label designed for wellness applications, share information about its interoperability features and provide similar consent mechanisms to enable its customers to make the choices best suited for them.

6.3 Supporting impact maximization of the EHDS

Looking at the narrow interpretation of the EHDS, it sets compliance requirements for wellness applications that interoperate with an EHR system in order to allow users of such apps to insert information into their own EHR. However, it is important to note that there are provisions of the EHDS that are not strictly meant for wellness applications but offer opportunities that Member States and manufacturers may want to embrace.

Suggestion 6: **Make Digital Testing Environments and/or other testing tools available to wellness applications.**

Although not mandated by Article 40, it would be beneficial for wellness applications manufacturers to be able to test these applications to be sure that they work as intended. Demonstrating the capabilities of interoperability features through testing could help to gain trust of the users, as well as healthcare providers that will store and use the data as part of the EHR. Further automated testing tools beyond interoperability (EEHRxF, semantic interoperability), such as for security testing, are promoted to support both self-declaration and third-party assessment, making these mandatory should be considered and perhaps supported in the EU database for registration of EHR systems and wellness applications [Article 49]. In France, a national test environment (https://interop.esante.gouv.fr/) is provided for free to all vendors willing to test the conformity of their application with interoperability standards. The environment is based on Gazelle and is also used for the certification of interoperability components.

Suggestion 7: **Consider an abbreviated version of the CEN-ISO/TS 82304-2 label as the EHDS label.**

Having an abbreviated ISO label for the EHDS may, especially if the full label is adopted by Member States, see suggestion 8, encourage manufacturers to pursue the desired development of wellness applications (and the wider scope of health apps) under ISO standards. The EHDS label proposed in Figure 9 demonstrates self-declared capabilities for data sharing, while the full ISO label adds third-party assessed scores on the quality and interoperability of the app and with a minor change as suggested in Figure 9 also includes the (sub-)categories of data generated by it for which interoperability has been claimed. As shown in this deliverable, the Label2Enable handbook for CEN-ISO/TS 82304-2 could be adjusted to accommodate all EHDS requirements allowing manufacturers that choose to adopt CEN-ISO/TS 82304-2 to prove compliance with EHDS, especially if coupled with the use of the Digital Testing Environment [Article 40] or other testing tools referenced in D5.1 and in our previous remarks on automated assessment tooling.

Including the abbreviated or if available the full label in the EU database or registration of EHR systems and wellness applications [Article 49] would enhance transparency and support trust.

Suggestion 8: **Improve the quality of the data by improving the quality of the wellness applications.**

EHDS does not set requirements for data quality (not just for wellness applications but overall), however, Recital 50 notes that Member States are free to regulate other aspects of wellness applications. Although different approaches in different Member States may act against the notion of the single market, we must recognise that healthcare is a national competence and if Member States choose to set additional requirements for EHR systems, they may also want to set requirements on the data quality intended to be added to an EHR. Adopting CEN-ISO/TS 82304-2 could help Member States to introduce such quality standards in a coordinated manner to support the implementation of the EHDS for the wider scope of health apps without contributing to fragmentation [Recital 7] adding as well to equity, as especially smaller Member States or languages would not be of interest to manufacturers if they would launch their own rigorous framework. Further expert support to Member States in such efforts is expected to support adoption decision-making and minimise context-specific requirements on top of CEN-ISO/TS 82304-2.

Suggestion 9: **Facilitate innovative new solutions by explaining how wellness applications may be able to benefit from EHR data when their user chooses to download data from the EHR system in the EEHRxF and to upload it into the wellness application.**

Wellness applications may benefit greatly from information stored in the wellness application user's EHR to personalise their services in order to support users in personal health management or prevention of diseases. However, the EHDS limit wellness applications to claiming interoperability for the purpose of inserting information in accordance with Article 5. Wellness app manufacturers would appreciate guidance on how to apply EHDS in a way that would make possible voluntary adoption of the EEHRxF that goes beyond inserting data in the EHR and allows the users to upload copies of their EHR data in their wellness application. This may include limitations (such as not to make EHR data accessible for the users on the device as it would qualify it as an EHR system, keep intended use for specified purposes only, after consent of the duly informed user, data storage location or manufacturer origin), safeguards (such as how EHR data will be processed by the wellness applications to meet data protection and safety requirements) and risks (if for example a wellness application does not adhere to high standards of cyber security). Experiences with the Dutch MedMij standard[98] and limiting exchange to personal health environments[99] and not e.g. step counters may be considered.

Suggestion 10: **Build on CEN-ISO/TS 82304-2 and Label2Enable deliverables as a basis for EHDS compliance**

Following up on several remarks in the first consultation, CEN-ISO/TS 82304-2 and Label2Enable deliverables were found adequate for use as a basis for EHDS compliance. However, further actions at EU and/or Member State levels are needed to make CEN-ISO/TS 82304-2 fit for purpose, including:

[98] https://medmij.nl/en/home/

[99] https://www.government.nl/topics/ehealth/question-and-answer/what-is-a-personal-digital-healthcare-environment

- the upcoming revision of CEN-ISO/TS 82304-2, for which a proposal is near final to submit, coupled with directions what to analyse, e.g., legislation flagged in Paragraph 3.3, if applicable specified standards not yet included in the handbook produced by Label2Enable as detailed in Paragraph 3.4 raised for instance in the second consultation, or ongoing initiatives which need further comparative analyses, see Paragraph 3.5,
- an assignment to harmonise the standard, to support EHDS, including guidance for market surveillance authorities and compliance with the wider EU legislative framework, keeping in mind that significant changes to wellness applications may place them over time under compliance frameworks such as the MDR and AI Act, this evolution may require decision-making in the build phase of the wellness application, as not every requirement can be built in later in the life cycle,
- making CEN-ISO/TS 82304-2 available free of charge and/or making the Label2Enable handbook an "HL7 implementation guide" for CEN-ISO/TS 82304-2. HL7 was already core expert (subject matter expert) for the CEN-ISO/TS 82304-2 quality aspect Robust build (which may be renamed Robust software), which includes the Interoperability quality requirements, and HL7 cMHAFF was one of the core documents which informed CEN-ISO/TS 82304-2,
- in case of using the Label2Enable handbook for CEN-ISO/TS 82304-2 as a basis, ensuring maintenance, and in case of an increasing demand for certification on a Member State or EU level, operationalizing the Label2Enable certification scheme, adding procedures and governance that were flagged but not yet developed or installed, ensuring smooth operations, considering policy recommendations from the Label2Enable project reviewers' end report.

As the implementing acts are due in March 2027, it should be clear very soon how to update CEN-ISO/TS 82304-2 and / or the Label2Enable handbook and/or the Label2Enable certification scheme to support the EHDS.

APPENDIX I XT-EHR WP8 SURVEY RESULTS FOR WELLNESS APPLICATIONS

In the frame of a survey that was conducted in May 2024 to a selected professional group from each one of the 30 participants from 25 Member States, significant conclusions were made. The purpose of this survey was to identify the status of the following topics in MS:

- EHR systems guidelines and harmonised requirements, including harmonised components of EHDS systems.
- EHR Conformity Assessment Scheme.
- Wellness application labelling guidelines.

This part provides the analysis of the 3rd part of the survey (questions 18 – 28) referring to the wellness applications and respective guidelines or requirements enforced by the Member States.
The results relating to wellness applications (and not medical devices) will be used to prepare guidelines supporting conformity and compliance assessment in EHDS and for adoption by the manufacturers aiming for harmonization and fulfilment of the new legal framework compliance.
Responses were received from 30 participants from 25 Member States.
Some of the Member States responded as a team while others responded individually. Multiple answers were allowed, and received from Croatia, Hungary, Ireland, and Spain. Poland and Belgium haven't responded to the survey. The results in diagrams are presented by responders and not per MS.

Survey aspects related to wellness applications

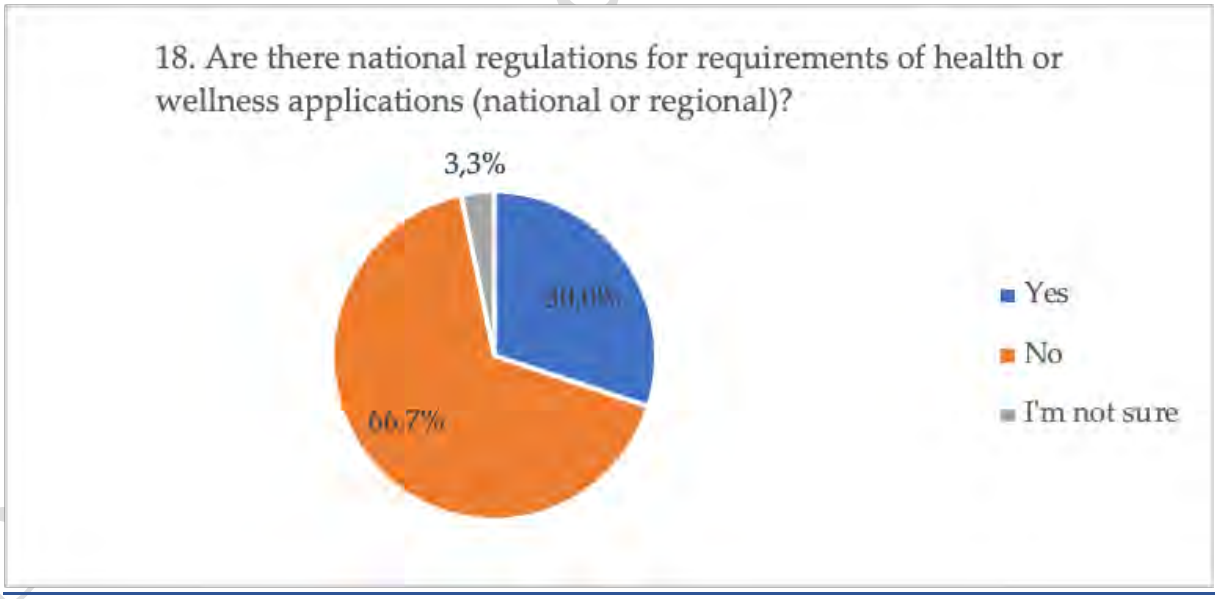


Figure 10 National regulations for requirements of health or wellness applications (national or regional)

The majority of 66,7% replied that there are no national regulations or requirements for health or wellness applications applying either at a national or at a regional level. 30% confirmed that they have such

provisions in the frame of the national regulations. There is a 3.3% claiming uncertainty on this matter. Positive answers were provided by Denmark, Finland, France, Germany, Norway, Spain and Sweden.

Denmark: Requirements are under development. A national board was established in 2024. The board's task is to assess quality of and recommend health apps to citizens and healthcare professionals in Denmerk. Assessment criteria are defined by the board and are not based on CEN-ISO/TS 82304-2, but aim to harmonize with European standards focusing on evidence for effect, user friendliness, fair price and societal value. The board deals with both health apps/medical devices and wellness apps. Recommended apps will be displayed on the official portal for the public Danish Healthcare Services, sundhed.dk. There is no reimbursement or any other formal advantages following a recommendation.
France: Listing the applications accessible to users of Mon Espace Santé.
Germany: Digital Health Applications (DiGA) must have successfully completed the assessment of the BfArM leading to a listing in a directory of reimbursable digital health applications (DiGA directory). The Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) has regulated the details of this procedure in the supplementary legal regulation, the Digital Health Applications Ordinance (Digitale Gesundheitsanwendungen-Verordnung, DiGAV). Further regulations are also given in Sections 33a and 139e of the German Social Code Book V (Fünftes Buch Sozialgesetzbuch, SGB V).
https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html
Norway:

- MDR
- The project "Safer Health Applications" aimed to facilitate better quality assurance of applications within the Norwegian healthcare system. It was led by the Directorate of Health and carried out in collaboration with the Norwegian Health Network and the Directorate for e-Health. The project lasted from October 2021 to November 2022. The evaluation framework is based on the requirements of "Health Software - Part 2: Health and Wellness Applications - Quality and Reliability (CEN-ISO/TS 82304-2:2021)," with adaptation to Norwegian conditions. The project assumed that health applications meeting the requirements to be classified as medical devices, and are certified and CE-marked, maintain a satisfactory level of safety for use in healthcare services. Therefore, the project was limited to creating an evaluation framework for the quality assurance of applications that are not categorized as medical devices, as this was identified as the greatest need. The project assessed that the requirements for non-medical applications could be somewhat less extensive than those outlined in the ISO document and that not all requirements in the standard are relevant for such applications. The project also aimed to include requirements used by the Norwegian Health Network to make health applications available on the national platform "Helsenorge", as well as other requirements specific to Norwegian conditions, so that suppliers and others would have a common evaluation framework to adhere to. The Norwegian Directorate of Health has recently published a recommendation for quality assurance of health and wellness applications based on CEN-ISO/TS 82304-2.

Portugal:

- General Data Protection Regulation (GDPR).

- European Medical Device Regulation (MDR) – applicable to apps that are medical devices.
- Decree Law n.º 83/2018, October 19: Sets the accessibility requirements of web sites and mobile applications from public bodies, transposing the 2016/2102 Directive.
- Applications must comply with general consumer protection laws that ensure transparency, accuracy of information, and user rights. This includes providing clear terms of service, accurate product information, and respecting user rights regarding digital content.

Spain:

- Data Protection Legislation: Health and wellness applications must comply with the General Data Protection Regulation (GDPR) and the Ley Orgánica de Protección de Datos Personales y garantía de los derechos digitales (LOPDGDD) in Spain, ensuring the protection of users' personal data.
- Medical Device Regulations: If a health or wellness app qualifies as a medical device according to the definitions set forth in European regulations (such as the Medical Devices Regulation - MDR), it may need to comply with applicable requirements for medical devices, including safety and performance standards.
- Consumer Protection Laws: Health and wellness applications are subject to consumer protection laws, which require transparency, accuracy of information, and fair practices in advertising and commercial transactions.

Sweden provided as a reference the MDR.

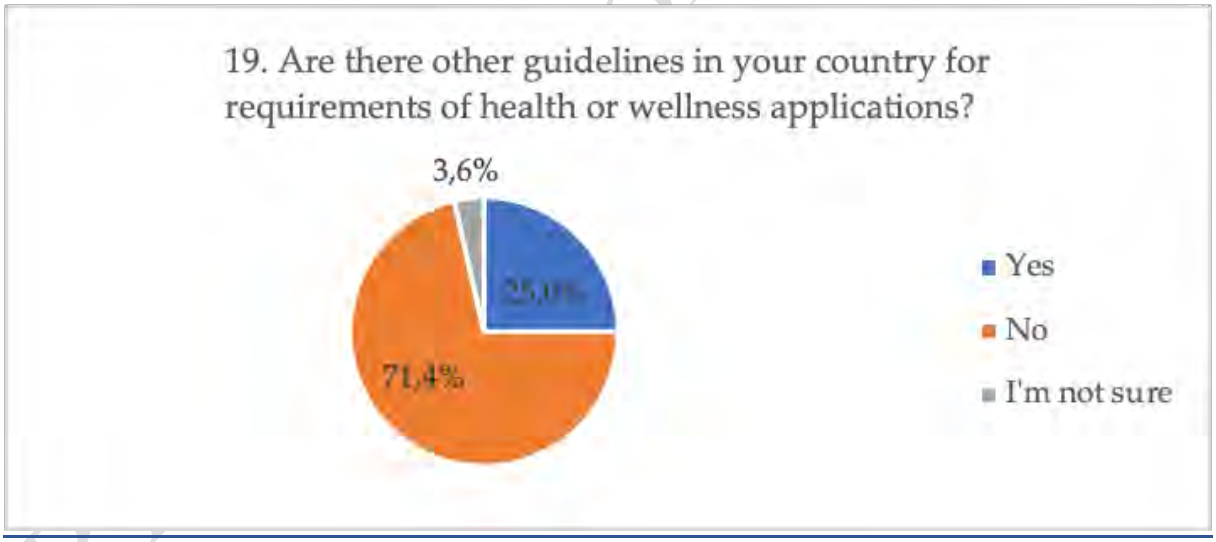


Figure 11 Other guidelines in your country for requirements of health or wellness applications

Only 25% of the participants replied that there are guidelines in relation to requirements for wellness and health applications. Among the positive responses were the following.

Denmark noted that most patients have an app called "My Doctor" for communication between GP and patient (new appointment, e-consultation etc.). This app is expanded with a list of recommended applications. No further references to guidelines on respective requirements or specifications.

Germany:

The requirements for DiGA are described in detail in the DiGA Guide (https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html).

Portugal:

The Usability and Accessibility Seal distinguishes the application of best practices for accessibility and usability in building sites and mobile applications. The initiative, developed by the Agency for Administrative Modernization, I.P. (AMA) and by the National Institute for Rehabilitation, I.P. (INR), aims to improve, simplify, and make it more efficient the use of online public services by citizens, primarily citizens with disabilities or disability. According to the 2021 census we are talking about 10.9% of the Portuguese. More information about the Usability and Accessibility Seal can be consulted under the following link. The Usability and Accessibility Seal consists of a set of accessibility and usability requirements, which are divided by three levels:

- At the Bronze level, we find x requirements divided into x categories. The Bronze requirements treat, in essence, the “Content” of websites and mobile applications. The Bronze Seal is particularly adjusted to websites and informative mobile applications.
- At the Silver level, we have added to the Bronze requirements, a set of x requirements divided into x categories covering the existing “Transaction” components on websites and mobile applications.
- At the Gold level, in addition to the Bronze and Silver requirements, websites or mobile applications need to be subjected to user testing. Thus, when a website or mobile application sports the Gold Seal, it is known that the same was the subject of a heuristic assessment of accessibility and usability requirements, validated by AMA, and usability testing with participants with disabilities or disability. By way of Decree-law No. 83/2018, of 19 October, in Portugal, the norm is the European Standard EN 301549. This standard corresponds to the standard W3C WCAG 2.1 level AA compliance. It is also recommended consulting the WCAG Success Criteria Map in a new window as an entry point in the W3C documentation.

Spain:

- EU Guidelines on the Medical Devices Regulation (MDR): Offers guidance for health app manufacturers on compliance with medical device regulations.
- EU Guidelines on Data Protection and Privacy: Outlines GDPR requirements for handling personal data collected by health applications.
- International Standards: ISO standards provide benchmarks for quality management and data security in health applications.
- Clinical Practice Guidelines: Recommendations from health authorities and professional organizations influence app adoption for managing conditions.
- Ethical Guidelines: WHO and professional associations provide ethical frameworks for app development and use.

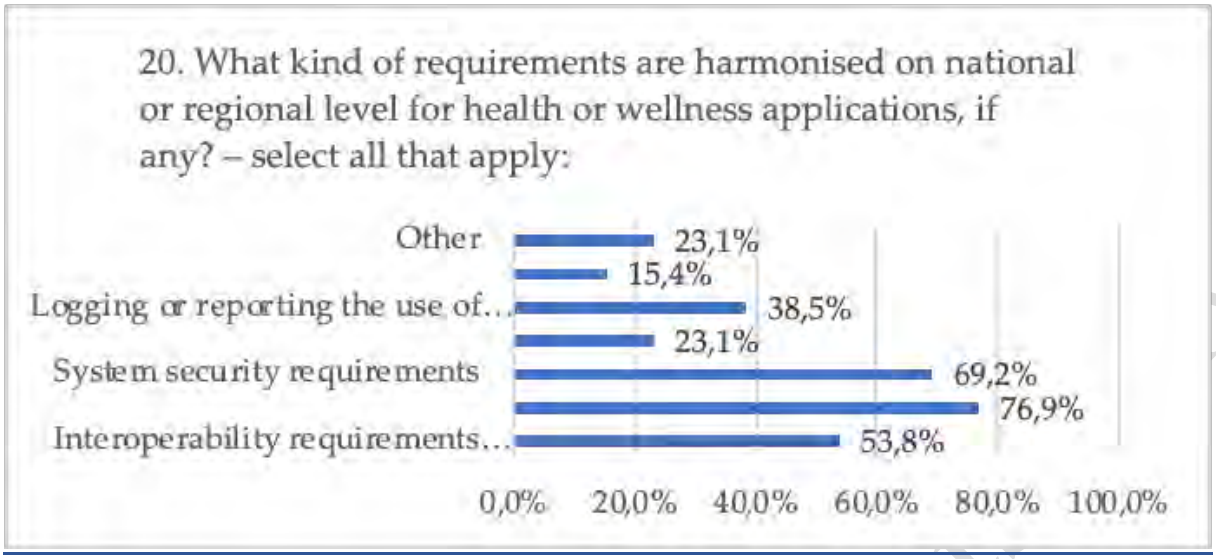


Figure 12 Harmonised requirements on national or regional level for health or wellness applications

In this question a diversity in the given answers by the Member States is noticed. A big percentage of 76,9 replied that harmonised requirements in their country are related to European and national data protection requirements, System security requirements, Logging or reporting the use of personal health data use in health and wellness applications. 69,2% replied that specified requirements are relevant to system security and 53,8% that the requirement correlate to interoperability concerning Interoperability requirements concerning data sets, code systems / terminologies, interoperability standards, interface / API specifications or implementation guides, European and/or national data protection requirements, System security requirements, Functional requirements or functions (or functional profiles) of health or wellness applications, Logging or reporting the use of personal health data use in health and wellness applications, Other. Logging or reporting the use of personal health data answers amount to 38,5% of the correspondents while 23,1% declares that they have functional requirements or relevant functions.

In the special section for the provision of more detailed information, it is important to highlight the following input coming from France, Germany and Portugal.

France: Functional requirements: see the data exchange portal. Order that publishes the set of applicable criteria: urbanization/interoperability/security/ethics. There is a distinction between mandatory and optional criteria. Order of October 23, 2023, amending the Order of June 23, 2022, relating to the criteria applicable to the referencing of digital services and tools in the service catalogue of the digital health space.

Germany:

- Interoperability requirements: Technical requirements for connecting DiGA to the EHR are defined in Section 6a DiGAV.

- European and/or national data protection requirements: Data privacy and data protection requirements are defined in Section 4 and Annex 1 DiGAV. These include that the application has to be compliant with the General Data Protection Regulation (GDPR). In the near future, proof of compliance with data protection requirements must be provided by submitting a certificate in accordance with Article 42 GDPR.
- System security requirements: System security/information security requirements are also defined in Section 4 and Annex 1 DiGAV. These include that a management system for information security (ISMS) according to ISO standard 27001 has to be implemented. In the near future, proof of compliance with information security requirements must be provided by submitting a certificate which is based on the Technical Guideline "BSI TR-03161 Security requirements for eHealth applications" (https://www.bsi.bund.de/EN/Themen/Unternehmen-und-Organisationen/Standards-und-Zertifizierung/Technische-Richtlinien/TR-nach-Thema-sortiert/tr03161/tr03161_node.html).

Portugal: Health and wellness applications in Portugal need to navigate a complex regulatory landscape that combines both national and EU requirements. Key areas include data protection, medical device regulations, certification standards, and approval from health authorities. Ensuring compliance with these requirements is crucial for the successful deployment and operation of such applications in the Portuguese market:

- General Data Protection Regulation (GDPR)
- Medical Device Regulation (MDR): If an app qualifies as a medical device, it must comply with the MDR (EU 2017/745).
- Decree-Law No. 145/2009: This law governs the manufacture, marketing, and use of medical devices in Portugal, aligning with EU directives.
- ISO 13485: A standard for quality management systems specific to medical devices, which can be applicable if the app is classified as a medical device.
- EN CEN-ISO/TS 82304-2-1: A standard providing guidance on the safety and quality of health software products.
- Secure Data Storage and Transmission: Implementing encryption and other security protocols to protect sensitive health information.
- Secure management of accounts and permissions: Implementing multi-factor authentication, principle of least privilege and role-based access controls, minimizing the risk of unauthorized access and data breaches.
- Logging and monitoring: Recording detailed information about system and user activities to track system behavior and diagnose issues as well as continuously monitoring system performance and health metrics to detect problems in real-time and ensure optimal operation.
- Backup and Recovery: Implementing regular backups and disaster recovery plans to ensure data integrity and availability in the event of a security breach or data loss.
- User Consent and Transparency: Clear communication to users about how their data will be used and obtaining informed consent.

- Health authorities:
  - o INFARMED: The National Authority of Medicines and Health Products in Portugal oversees the regulation of medicines and health products, including medical devices.
  - o DGS (Direção-Geral da Saúde): The Directorate-General of Health provides guidelines and oversight for public health in Portugal, which may include digital health solutions.
- Usability and Accessibility: Web Content Accessibility Guidelines (WCAG).

Figure 13 National, regional, project-based or commercial testing or experimenting practices such as hackathons, national / regional testing events, sandboxes, commercial testing services - for interoperability, data protection, security, functionality or other

Only 25 % of the responding countries declared that they conduct or follow such procedures. 57,1% declared that they don't have such mechanisms and 17,9% there is uncertainty or no available information.
Croatia noted the website for the hackathon event: http://www.hzzo-net.hr/hackathon/.
Germany stated that many DiGA-manufacturers are organized in a registered association, which offers a "Bug-Bounty-Program" to increase data security. Hackathons concerning interoperability have previously been offered by the gematik.
Italy stated WIP for telemedicine services technical validation process as evaluation step for inclusion in the national catalogue for health applications (wellness apps excluded).
The Netherlands:
National level: designathons for usability & interoperability, living labs for usability, test en validation services for interoperability. In addition the testing as required per the MDR regulations on a local/regional level. On a hospital level several initiatives for functional testing and testing patient experiences.
Portugal referred in detail to the relevant local events:

- Health 2.0 Porto: This event brings together manufacturers, designers, healthcare professionals, and entrepreneurs to collaborate on innovative health tech solutions. Participants often work on interoperability, data protection, and usability aspects of health applications.
- Portugal Health Cluster: This organization collaborates with various stakeholders to promote innovation in health. It runs projects that often include testing phases for new health technologies.
- CoLab (Collaborative Laboratories): Projects within CoLabs, such as the Healthy Aging CoLab, focus on developing and testing health tech solutions with an emphasis on usability and functionality.
- InnoStars Awards: A part of the EIT Health initiative, this program includes mentoring and testing services for health tech startups, focusing on the commercial viability and usability of health applications. ANI (National Innovation Agency): Supports various projects and initiatives that include testing and validation phases for health technology solutions, ensuring compliance with national and European standards.

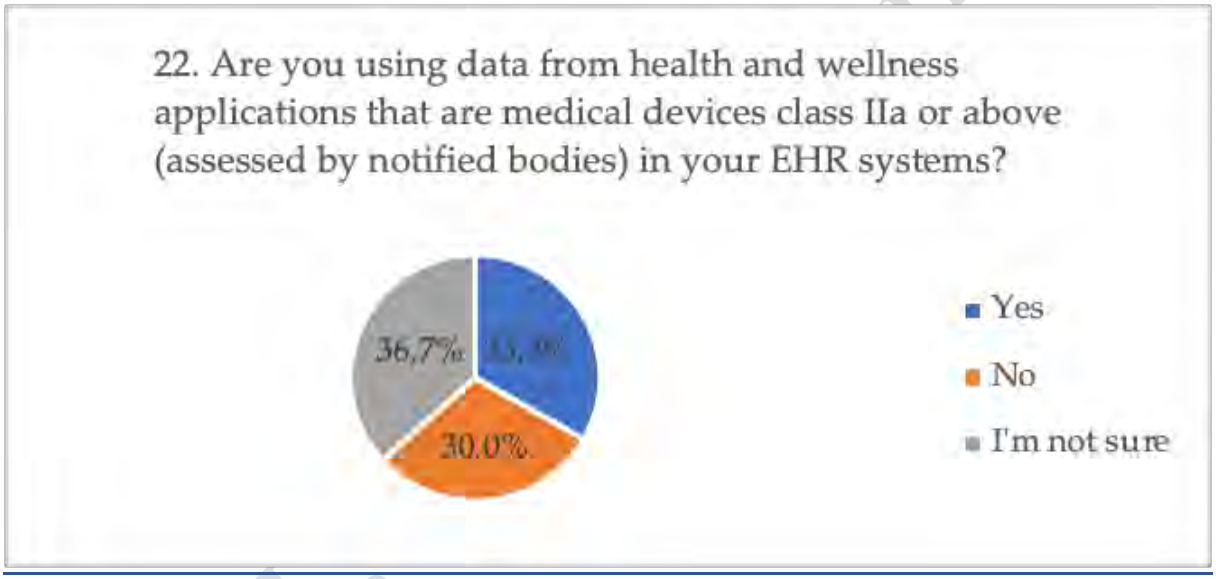


Figure 14 Use of data from health and wellness applications that are medical devices class IIa or above (assessed by notified bodies) in the EHR systems

Interesting is the fact that 36,7% of the answers reflect uncertainty (Not sure) on this matter which may be interpreted by awareness gaps or confusion in terminologies and definitions of health and wellness applications also in relation to MDR categorisation. 33% stated that there is no use of data from health and wellness applications that are medical devices class IIa or above (assessed by notified bodies) in the EHR systems. 33,3% answered that they do use this category of data and, in specific:

Estonia: Only health applications that are interoperable with central system but no wellness applications.

France: The data exchange pathway is open, the data shared are health measurements, calendar data, documents. Referencing of applications is ongoing.

Germany: With the connection of DiGA to the EHR, which is currently being implemented by the different DiGA manufactures, it will be possible for patients in Germany to transfer data from DiGA to their EHR.

Italy: Currently at local level; we are working to include data from health applications (no wellness) at national level according to EHDS regulation.
Lithuania: There are some initiatives in a narrow context, at the hospital level, but not at the national level.
The Netherlands: I'm not totally sure what types of medical devices are meant here. All types, mainly health and wellness applications (software as a medical advice) or remote patient monitoring devices. The implementation of medical devices in the EHR in the Netherlands is limited. Some smart medical devices such as infusion pumps can feed information into the EHR. For CDS tools, some tests exist in which they are built into the system, some are built to work around the system (attached to the database behind the EHR, accessed via an external software environment. It is not standard yet and is related to the EHR-manufacturer. (vendor lock-in). E.g. Chipsoft Hix (EHR tool) has a class 2b MDR certification. I'm not sure for which part of the tool. It might be associated with prescription of medication, often software as a medical device is used in separate applications outside of the EHR (e.g. radiological tools).

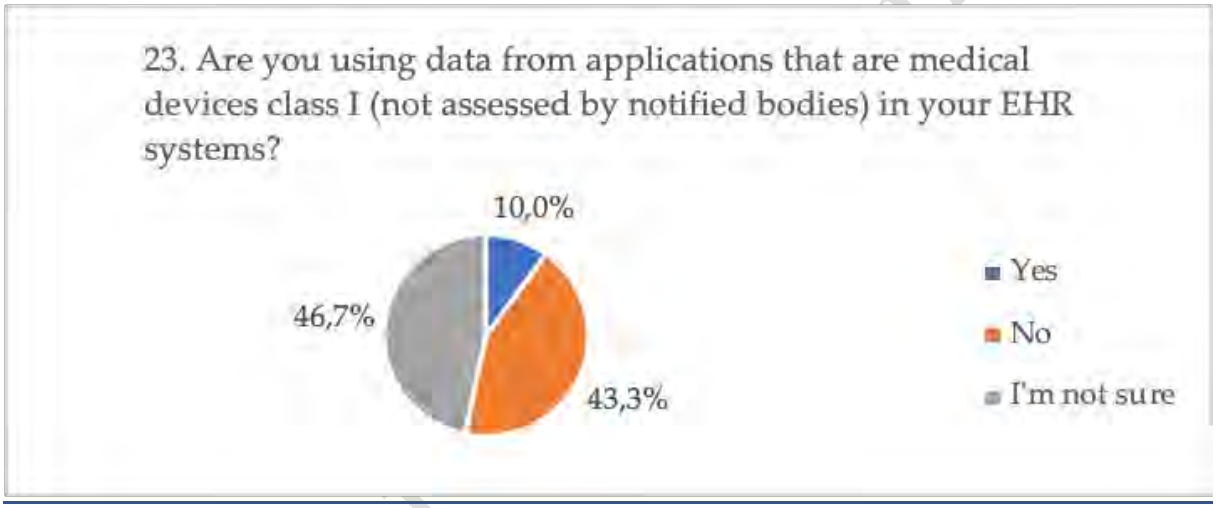


Figure 15 Use of data from applications that are medical devices class I (not assessed by notified bodies) in the EHR systems

Uncertainty to answer about the use of data under class I applications, is significant and reached the percentage of 46,7% - nearly half of the participants. Only 10% responded that this type of data is used. For example,
France: The data exchange pathway is open, the data shared are health measurements, calendar data, documents. Referencing of applications is ongoing.
Germany: With the connection of DiGA to the EHR, which is currently being implemented by the different DiGA manufacturers, it will be possible for patients in Germany to transfer data from DiGA to their EHR.
The Netherlands: ''*I assume that we are talking about the MDR legislation and not the old MDD legislation in which most software were class 1. Not many software devices are MDR class 1. I know some separate applications are available, but not yet linked to the EHR. One of the issues is the compatibility between systems and standards. Compatibility with the EHR is an issue*.''

Portugal: *"Some EHR systems are already receiving data from applications that are medical devices, however, we do not have information regarding class type and coverage percentage for this survey. In addition, there are also close systems that receive data from a predetermined set of medical devices, such as those defined in telemonitoring platforms"*.

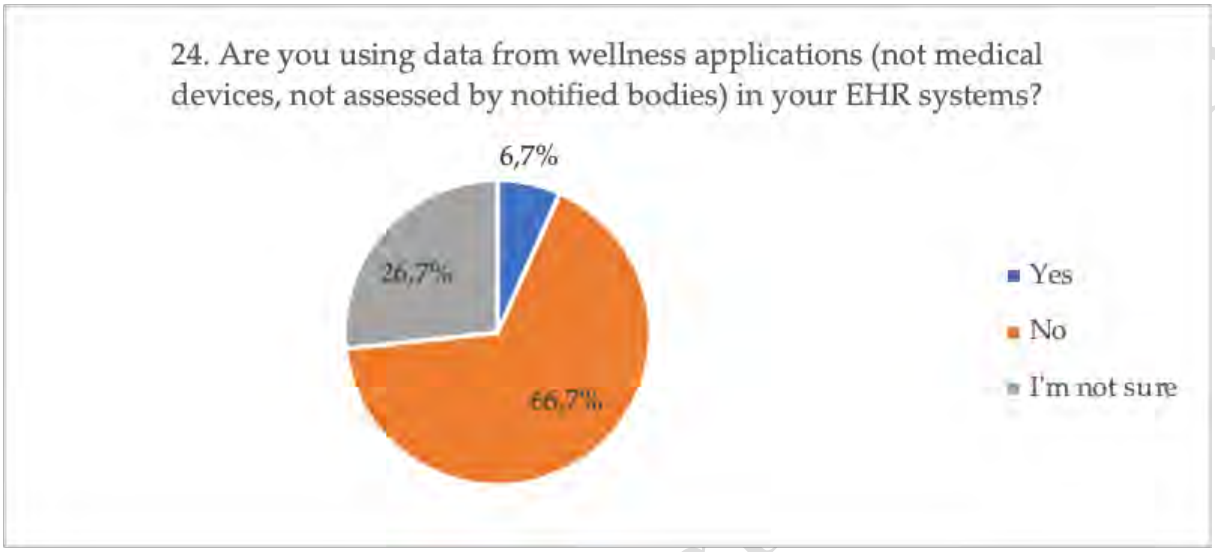


Figure 16 Use of data from wellness applications (not medical devices, not assessed by notified bodies) in the EHR systems

66,7% responded that there is no use of data from wellness applications in the EHR systems used in the respective countries. 26,7% stated use of such data in EHR systems.

Portugal replied that data from wellness applications is used on the following Portuguese EHR systems:

- SNS 24: national eHealth mobile application that allows citizens to access a wide range of digital health information and services, such as patient summary, eP/eD, eP of exams and results, immunization card, etc.
- Telemonit SNS24: national mobile application where users can access their prescribed clinical monitoring plan proposed by the healthcare professional who monitors them.

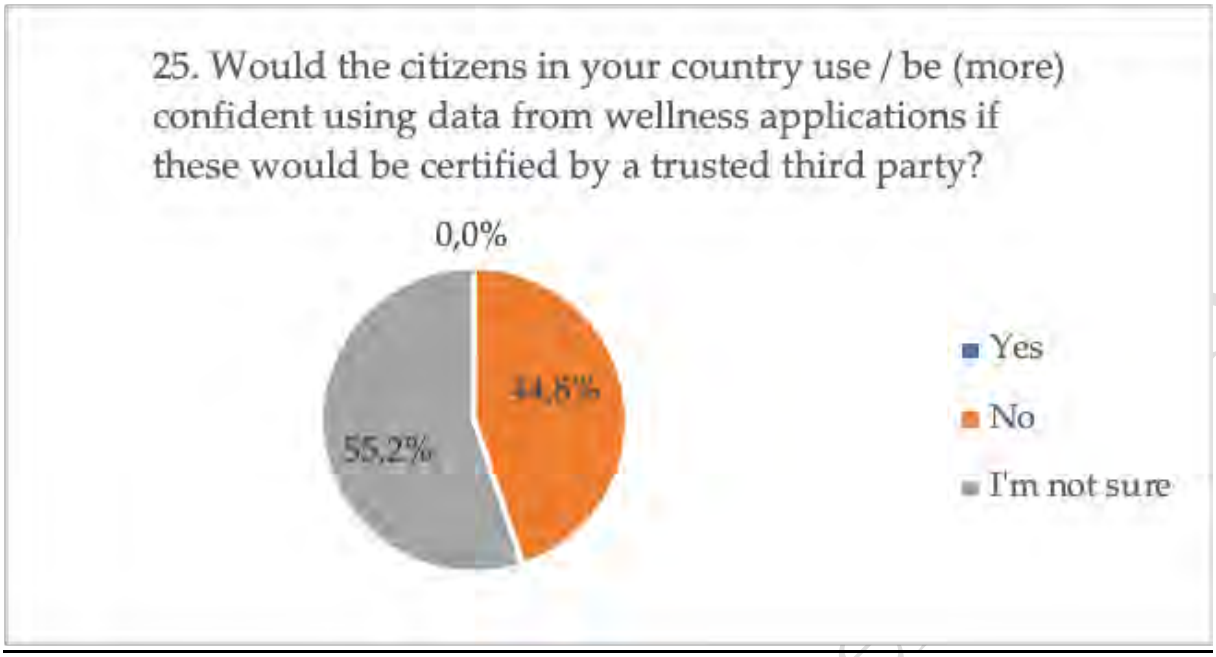


Figure 17 Citizens use / would be (more) confident using data from wellness applications if these would be certified by a trusted third party

44,8% answered that certification of applications by a third-party would have no impact on the confidence in using data for the users and 55,2% that they are not sure. This matter has to be further elaborated, and reasons must be further explored to identify either cultural and awareness issues or market attitude perspectives that should be enforced.

[Note: The Label2Enable Task 4.2 (D4.1) survey asked: Do you think the government should review and rate health app quality (not distinguishing between health and wellness apps) to help you choose a health app? In total 1228 responded of which 664 (54%) answered yes, 396 (32%) thought the government should pay another organisation to review and rate apps, 168 (14%) voted no. A similar survey in Australia produced even higher support rates for the government reviewing and rating health apps or paying another organisation to do so.]

Italy noted that questions 25 to 28 related to wellness applications are currently out of scope for Italian public authorities as the only sector covered is Medical Device regulation.

Figure 18 Health service providers use / would be (more) confident using data from wellness applications if these would be certified by a trusted third party

This is a similar question but for the healthcare services providers and their confidence in using data from wellness applications in the case these are certified by a trusted third party.
51,7% replied positively which reveals an increased awareness on the matter in healthcare providers (a more specific target group of opinion makers on this matter).
Uncertainty about the matter remains high, at a percentage of 41,4% (possibility for a positive impact).
Only 6,9% gave a negative answer.
Portugal noted that ''*data from wellness applications is often entered by the end user or comes from measuring equipment. If an XIS. I see no role here for a third party that would have a certifying role. A characteristic that data has been entered by the person himself can be valuable*''.

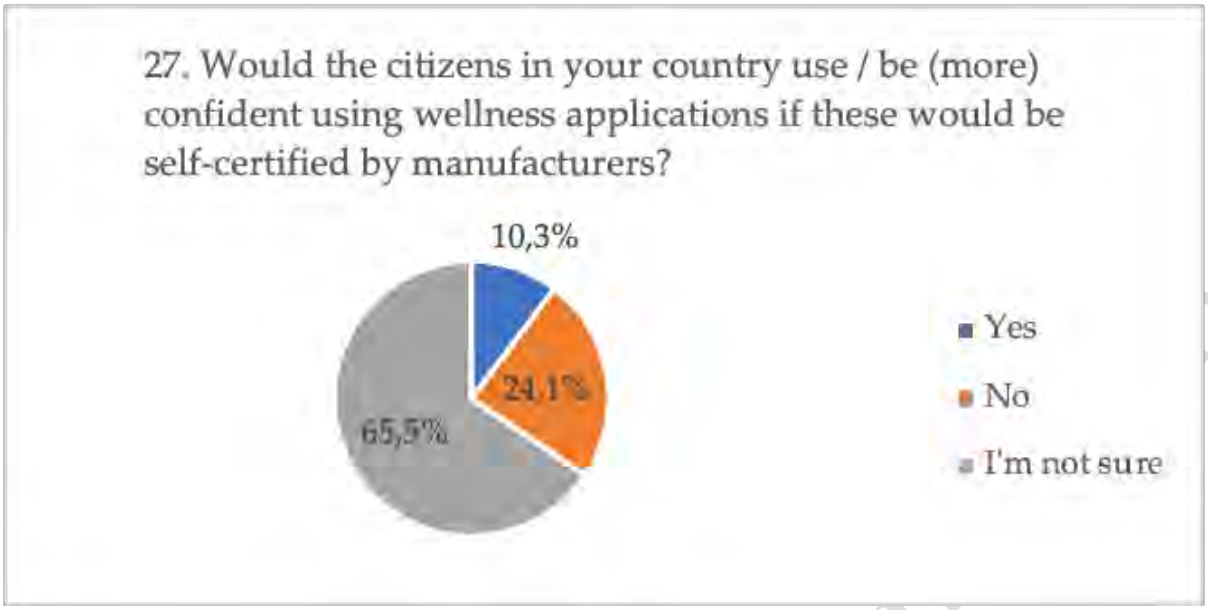


Figure 19 Citizens use / would be (more) confident using wellness applications if these would be self-certified by manufacturers

This question examines the increase of confidence of the citizens using wellness applications in case of self-assessment of manufacturers. A positive answer was only given by 10,3%.
24,1% answered negatively and 65,5% reflected a probable correlation (uncertainty remains high).

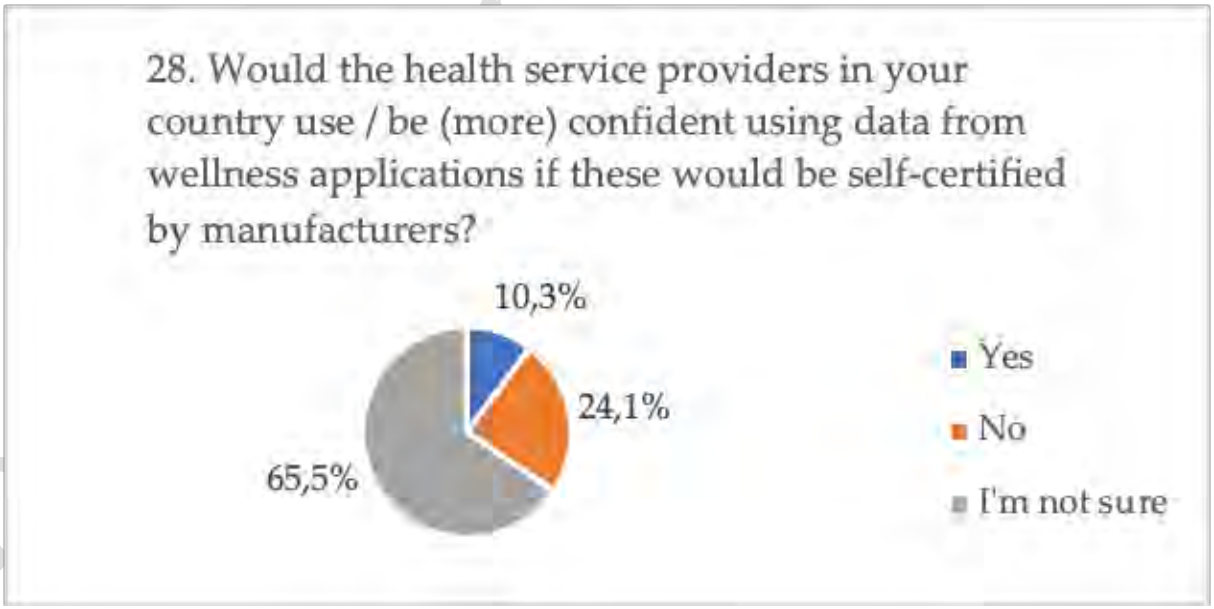


Figure 20 Health service providers use / would be (more) confident using data from wellness applications if these would be self-certified by manufacturers

For the healthcare providers the positive answer is 10,3% - significantly lower in comparison to the response that referred to third-party certification, which may be explained by the fact that the selected target group of healthcare providers rely more on independent body certifications rather than on self-assessment schemes.

Czech Republic: Self-certification of wellness applications (pursuant Regul. on the EDHS) relates only to interoperability of the applications, so confidence may be similar as in the case of EHR systems.

Sweden: In general Sweden wants assessed and certified products to trust the usage.

APPENDIX II APPLICABILITY CONTENT D5.1 WITH REGARD TO ANNEX II FOR WELLNESS APPLICATIONS

To enable alignment of the D5.1 interpretation of Annex II for EHR systems and the D8.3 Annex II interpretation for wellness applications, the D5.1 content was evaluated in this Appendix. As further decision-making as to the D5.1 interpretation of Annex II is yet to occur, this is merely displayed as an overview and in colour codes in Figure 8.

Annex II Section 1.1 - interpreted as not applicable for wellness applications

If Section 1.1 would be considered to apply *mutatis mutandis* for wellness applications, and the rationale of D5.1 would be followed, the following CEN-ISO/TS 82304-2 quality requirements may be considered to apply to wellness applications for which interoperability is claimed to align with the D5.1 interpretation.

D5.1 3.1.2.1 The EHR system shall operate reliably under real-world workflows and use cases, could be a rationale for considering CEN-ISO/TS 82304-2 **5.5.1** (Technical robustness, 8 requirements). The system shall demonstrate performance for an intended purpose, in expected environment may be reason to consider CEN-ISO/TS 82304-2 **5.2.1.2** (restrictions in intended users clear), **5.2.4.3** (costs to achieve health benefit - e.g., use additional services or other products), **5.2.4.4** (needed support HCP to achieve health benefit), **5.2.4.5** (evidence health benefit), **5.2.4.5.1** (evidence health benefit includes peer reviewed research with this app), and **5.2.4.5.2** (level of evidence is appropriate). The list of intended uses of a health app in CEN-ISO/TS 82304-2 is included in Chapter 2 of this deliverable. The system shall enable testing may be reason to consider **5.4.2.10** (security tested on a regular basis and at major changes) and **5.5.1.6** (validation and verification plan).

D5.1 3.1.2.2 and 3.1.2.3 relate to patient safety features and risk management in design and may be reason to consider CEN-ISO/TS 82304-22 **5.2.2** (health risks, 5 requirements), CEN-ISO/TS 82304-2 **5.3.2.4** (prevent use error), and potentially CEN-ISO/TS 82304-2 **5.3.1** (accessibility, 5 requirements), **5.4.2.2** (information security risk assessment) and **5.4.2.3**(secure by design). As wellness applications are not intended to include medical devices risks may be considered acceptable, however the Label2Enable handbook listed potential risks for both wellness applications and medical devices, requiring both to analyse health risks. Meeting this requirement is even one of the 4 mandatory minimum requirements to qualify for an CEN-ISO/TS 82304-2 label.

D5.1 3.1.2.4, documentation of intended use, relates to CEN-ISO/TS 82304-2 **5.2.1.1-4** (intended users and intended use, 4 quality requirements of which 1 score-impacting), **5.2.2.4-5** (limitations of use, 2 quality requirements of which 1 score-impacting), **5.2.4.1** (description benefit of the app, not score-impacting), **5.2.4.3** (costs to achieve health benefit - e.g., use additional services or other products), **5.2.4.4** (needed support HCP to achieve health benefit), **5.3.2.3** (testing user-centredness) **5.3.2.5** (product information) and most of CEN-ISO/TS 82304-2 **5.5.1** (technical robustness, 8 requirements) or perhaps even the overarching CEN-ISO/TS 82304-2 **5.5** (robust build, 12 requirements), e.g. **5.5.2.1** (given data flow

diagram). Also **5.1.1.4** (languages), **5.3.2.6** (instructions for use) and all 5 requirements of **5.3.1** (accessibility) may be considered.

Annex II Section 1.2 - interpreted as not applicable for wellness applications

If Section 1.2 would be considered to apply *mutatis mutandis* for wellness applications, and the rationale of D5.1 would be followed, the following CEN-ISO/TS 82304-2 quality requirements may be considered to apply to wellness applications for which interoperability is claimed to align with the D5.1 interpretation.

D5.1 3.2.2.1 (supply and distribution requirements), 3.2.2.2 (installation requirements) and 3.2.2.4 (documentation requirements) relate to CEN-ISO/TS 82304-2 **5.3.2.6** (instructions for use), perhaps **5.5.1.6** (validation and verification) and **5.5.1.7** (release and deployment), and considering recommended hardware **5.2.4.3** (products needed) and although obvious and not feasible for use otherwise **5.1.1.1** (operating systems) might be considered to apply.

D5.1 3.2.2.3 (performance integrity requirements) relates to CEN-ISO/TS 82304-2 **5.5.1.5** (load testing), **5.5.1.6** (verification and validation), **5.5.1.7** (release and deployment), and **5.5.1.8** (maintenance process). A difference between EHR systems and wellness applications is that in the case of wellness applications these activities are executed by the manufacturer, and not by installers or system administrators.

Given the difference in intended users, wellness applications are for use by natural persons, which may also include persons with disabilities and limited (health / digital) literacy , the 5 CEN-ISO/TS 82304-2 **5.3.1** (accessibility) requirements [Recital 7: Any digital transformation in the healthcare sector should aim to be inclusive and also benefit natural persons with limited ability to access and use digital services, including people with disabilities] may be considered. Also, the not yet specified **5.3.2** “usability” requirements, which include e.g. if intended users were involved pre-design (**5.3.2.1**), in design and development (**5.3.2.2**), user-centred testing (**5.3.2.3**) and post-market research (**5.3.2.8**) of wellness applications, and if help is available if people get stuck (**5.3.2.7**) despite the product information (**5.3.2.5**) and instructions for use (**5.3.2.6**) may be considered to apply if *mutatis mutandis* is interpreted as applicable.

Annex II Section 1.3 - interpreted as applicable for wellness applications

D5.1 3.3.2.1 (interoperability requirements), in particular the EHR system shall adopt HL7 FHIR and DICOM/DICOMweb and using recognized terminologies for semantic interoperability are considered covered in CEN-ISO/TS 82304-2 **5.5.2.1** (APIs) and **5.5.2.2** (terminologies).

D5.1 3.3.2.2 (upholding rights of natural persons), objective: Align technical features with broader legal obligations for rights of natural persons under EHDS Chapter II and data protection regulations (e.g., GDPR, national regulations on personal data). The Label2Enable handbook for CEN-ISO/TS 82304-2 flagged 14

CEN-ISO/TS 82304-2 quality requirements that are or may be required by the GDPR and as such may be considered mandatory within the EU for health and wellness apps, see Chapter 4 in this deliverable for a list**.** Label2Enable did not consider national regulations. Although not mandatory according to the GDPR, for accessibility [Recital 7] and privacy literacy purposes CEN-ISO/TS 82304-2 **5.4.1.1.4.1** may be considered (privacy statement starts with accessible overview).

With regard to EHR systems needing to separate inserted information from patients from the electronic health data created and inserted by health professionals, we assume that the EEHRxF includes an identifier for patient-provided data. Also, for consideration, apps designed to be used by vulnerable people may want to provide a possibility of distinguishing between data captured or inserted by the data subject (patient) or a representative, e.g. for children, persons with limited or declining cognition, mental issues, severe illness, motor issues, visual impairment, limited disease insight, eating disorders, other vulnerable persons, to enable health professionals to consider the inserted data accordingly.

D5.1 3.3.2.3 (purpose of use logging) does not apply to wellness applications as their intended users are natural persons and not health professionals.

D5.1 3.3.2.4 (compliance monitoring): An additional note to support the manufacturer was added to **5.5.2.1** pointing out claiming interoperability entails a change to **5.5.1.1** (product requirements), which would then also affect **5.5.1.6** (validation and verification plan). Article 47(7) includes the role of market surveillance authorities to check compliance of wellness applications with the essential requirements laid down in Annex II. Meeting evolving regulatory requirements and technical standards with a broader lens may refer to CEN-ISO/TS 82304-2 **5.2.1.5** (medical devices, which wellness applications may evolve to after significant changes), and alignment with GDPR as detailed in Chapter 4 in this document. Alignment of the handbook for CEN-ISO/TS 82304-2 with EU legislation within Label2Enable did not include national legislation. Alignment with technical standards is addressed every 3-5 years in the revision of an ISO standard. CEN-ISO/TS 82304-2 was published in July 2021; a revision is being prepared and related funding applied for. Intent is to evolve the CEN-ISO 82304-2 Technical Specification (TS), which was labelled high impact by ISO and unanimously supported in the latest CEN-ISO ballot (18 countries: 10 confirm, 8 revise, 0 withdraw) and IEC ballot (11 countries: 3 confirm, 8 revise, 0 withdraw), to an International Standard (IS).

D5.1 3.3.2.5 (other recommended best practices): Nothing to add.

Annex II Section 1.4 - interpreted as applicable for wellness applications

D5.1 3.4.2.1 (interoperability requirements): For wellness applications sharing within the scope of the EHDS is one way [Article 5 - right to insert], not bidirectional, and only to the extent that the wellness application manufacturer claims interoperability [Article 47] and the user has chosen to share categories of personal electronic health data and related circumstances and provided consent [Article 48(2)]. Related requirements are for wellness applications already covered under **5.5.2.1** (APIs) and **5.5.2.2** (terminologies)

and Chapter 5 as a result of the analysis in Chapter 4 of this deliverable. If a wellness application claims interoperability it will need to (have an API of its own,) use the EEHRxF and adhere to further guidance from the EHR system to be able to insert data by means of the European interoperability software component / API the EHR system is to provide.

D5.1 3.4.2.2 (security and reliability) may provide guidance to manufacturers. The mandatory requirement (the system must ensure reliable and secure data sharing) in itself is not specific enough to require notes in the Label2Enable handbook. If the recommended features / best practices would be adopted and affect wellness applications, which (iii) seems to suggest, further notes and assessment sub-questions reflecting the content of the D5.1 recommended features / best practices may be added to CEN-ISO/TS 82304-2 **5.4.2.8** (encryption) and **5.5.2.1** (APIs). Although technically outside the scope of the EHDS as EHDS does not intend to regulate import of data in wellness applications, if the D5.1 3.4.2.2 objective would be followed, CEN-ISO/TS 82304-2 **5.5.2.3** (validate data import) may be considered.

D5.1 3.4.2.3 (operational performance) Similarly, although technically outside of the scope of the EHDS, as EHDS does not intend to regulate response times of wellness applications, the related CEN-ISO/TS 82304-2 requirement is **5.5.1.5** (deal with increase or spike in demand)?

D5.1 3.4.2.4 (compatibility validation) seems to not significantly differ from 3.4.2.1, perhaps the difference is the emphasis on real-world actual functioning compatibility. Again, the recommended features / best practices may affect the handbook if wellness apps would need to / could use the testing software suggested here (or in Article 40). Lifecycle management is specified as well for external products. This relates to CEN-ISO/TS 82304-2 **5.5.1.6** (validation and verification plan) and **5.5.1.7** (release and deployment process) and perhaps also **5.4.2.4** (ensure third-party software libraries and components are reliable and maintained).

Annex II Section 2.1 - interpreted as not applicable for wellness applications

There may be potential for automated assessment of wellness applications given D5.1 4.1.2.4 recommended features / best practices (use automated checks to confirm data fields match EEHRxF definitions, on terminologies, coding standards and value sets, depending on the national infrastructures, such validations procedures can be facilitated by means of centralised terminology services). Could these be made available open source, similar to the testing software referred to in Article 40 both for manufacturers and assessment organisations?

Other than that, not applicable.

Annex II Section 2.2 - interpreted as not applicable for wellness applications

D5.1 4.2.2.2 (format validation) and 4.2.2.3 (security and privacy compliance) confirm that the only check that the EHR system will do is to ensure inbound data aligns with EEHRxF schemas and is free from format errors or semantic errors and not corrupted during transmission. These checks do not include an evaluation of the usefulness and quality of the data from a healthcare purpose perspective. Current EHR system practices with regard to inserting personal electronic health data from apps include policies to avoid “garbage in, garbage out”. This and the effect that not knowing the quality of data originating from an individual wellness application may increase concerns with regard to data quality for all wellness applications, could be reason to reconsider applicability of Annex II Section 1.1 (and relatedly Section 1.2) for wellness applications or adoption on Member State level.

Annex II Section 2.3 - interpreted as applicable for wellness applications

D5.1 4.3.2.1 (data reception capability) and D5.1 4.3.2.2 (validation and error handling) confirm inbound data must be properly recognized (as patient-provided data of a particular patient in the case of wellness applications), validated (presumably as detailed for Section 1.4 and 2.1) and stored / processed. Decision-making on the recommended features / best practices with regard to APIs and semantic alignment may require a further note to CEN-ISO/TS 82304-2 **5.5.2.1** (APIs) and **5.5.2.2** (terminologies) and benefit from assessment tooling.

D5.1 4.3.2.3 (security and privacy compliance) recommended feature / best practice encrypted channels (e.g. TLS 1.3 or higher) for data transfer, ensuring data is protected in transit, relates to CEN-ISO/TS 82304-2 **5.4.2.8** (encryption).

Annex II Section 2.4 - interpreted as applicable for wellness applications

D5.1 4.4.2.1 (granularity standards) recommended feature / best practice (i) is already covered in CEN-ISO/TS 82304-2 **5.5.2.2** (terminologies) - if need be ATC for medications and other recognized standards can be added with a note to the Additional guidance and evidence, (ii) can be further specified in CEN-ISO/TS 82304-2 **5.3.2.4** (prevent use error): *Does the evidence supplied and a check in the app confirm: 4. if measurements that require manual input, measures such as dropdown menus are used in case of limited response option, out of range options are not accepted and understandable to-the-point messages (e.g., auto-complete fields), alert the user and if applicable the health professional how to proceed adequately?*

D5.1 4.4.2.2 (mandatory field validation) (ii) is addressed by CEN-ISO/TS 82304-2 **5.3.2.4** as detailed at 4.4.2.1.

D5.1 4.4.2.3 (interoperable data structures) is considered a responsibility of the wellness app manufacturer to achieve inserting patient-provided data, as addressed already under Annex II 1.3. Of note, while the data sits in the wellness app, it is not a priority category. It will only become part of the priority category

(patient-provided data) AFTER being inserted into an EHR, and is not expected to include more priority categories.

D5.1 4.4.2.4 (user interface and workflows) is considered captured with the additional sentence to the existing note 3 of the Additional guidance and evidence for CEN-ISO/TS 82304-2 **5.4.1.1.2** (data minimization). If recommended feature / best practice (i) (multi-language support) is adopted, a further note and related sub-question for assessment purposes should be considered for CEN-ISO/TS 82304-2 **5.1.1.4** (languages), which may make it a score-impacting CEN-ISO/TS 82304-2 requirement, and/or perhaps **5.3.2.5** (product information) pointing towards a list of official EU languages. Differences in units of measurement per language / Member State, could be obtained by **5.2.1.6** (involvement of health professionals in development app).

D5.1 4.4.2.5 (compliance testing) would as suggested in recommended feature / best practice (iv) require automated compliance audits. See previous remarks on making automated compliance tooling available open source for use by wellness app manufacturers and app assessment organisations.

Annex II Section 2.5 - interpreted as not applicable for wellness applications

D1 4.5.2.6 (data subjects compliance under data protection legislation and EHDS) recommended features / best practices are for the most part already addressed in the Label2Enable handbook for CEN-ISO/TS 82304-2. Those specific to the EHDS may need additional notes and subquestions for assessment once more detail is available:

(i) DPIA: CEN-ISO/TS 82304-2 **5.4.2.2** (information security risk assessment)

(ii) legal agreements for data sharing with third parties: Not applicable

(iii) retention policies: CEN-ISO/TS 82304-2 **5.4.1.1.3** (retention policy).

(iv) notice to data subjects of the possibility to make complaints with authorities if their data export rights are restricted [Articles 21, 22, 100]: specific to EHDS yet does not seem to apply to wellness applications as this would force a wellness application to claim interoperability. If that would be the case, more details would need to become available to adequately guide manufacturers. Depending on the details the related CEN-ISO/TS 82304-2 requirement can be determined.

(v) notice for patients with information required by Article 13 GDPR (at minimum): CEN-ISO/TS 82304-2 **5.4.1.1.4** (privacy statement), and to contribute to privacy literacy and inclusiveness, mindful of the practice to just click yes instead of having to read a manifold page document: **5.4.1.1.4.1** (privacy statement starts with an accessible overview of less than 150 words).

Annex II Section 2.6 - interpreted as not applicable for wellness applications

D5.1 4.6.2.2 (data portability standards) mandatory requirement "the exported data must conform to EEHRxF, ensuring compatibility with replacement systems across Member States" would seem not proportional to wellness applications, which may choose to claim interoperability. The topic is addressed though in CEN-ISO/TS 82304-2 **5.5.2.4** (data export to another platform).

Annex II Section 3.1 - interpreted as not applicable for wellness applications

Authentication, authorization and session management is addressed in the Label2Enable handbook for CEN-ISO/TS 82304-2 **5.4.2.7** for users (natural persons) themselves. This includes strong authentication methods such as multi-factor authentication, session timeouts and logging activities of the data controller, depending on their capacity to change, add or delete data.

Annex II Section 3.2 - interpreted as not applicable for wellness applications

Nothing considered specific to wellness applications.

Annex II Section 3.3 - interpreted as not applicable for wellness applications

Early detection and security-incident response procedures are addressed in the Label2Enable handbook for CEN-ISO/TS 82304-2 **5.4.1.1.8** (security-incident response procedures) and **5.4.2.9** (security vulnerabilities identified and resolved). Logging for wellness applications is considered beyond the scope of the EHDS.

Annex II Section 3.4 - interpreted as not applicable for wellness applications

D5.1 5.4.2.1 (configurable retention policies) Retention periods with regard to patient-provided data are not specified, nor if these may differ per EHR system. This may affect the responsibility of a wellness app manufacturer to duly inform a user (natural person) of the effects of interoperability [Article 48(1)]. Guidance as to generally accepted retention periods or a standardized script that wellness app manufacturers could use to duly inform users (natural persons) about retention periods would, if retention periods are considered within the scope of "duly inform", be helpful.

Our assumption is that the origin of health data does not need to be further specified and thus provided in the EEHRxF by a wellness app, than on the level of that app, even if the app has retrieved part of its

content from other sources than the user, perhaps even from an EHR system. CEN-ISO/TS 82304-2 **5.5.2.3** addresses the need to ensure data retrieved from elsewhere is quality data.