

HEALTH APPS DIFFER IN QUALITY AND RELIABILITY

Scientific evaluation of effectiveness and safety of mHealth has not kept pace with the growing commercial health app market. Some apps have a positive, others a negative effect on health, safety or data security. Yet, it is hard to impossible to identify the good ones in app stores or online.² To enable more informed decisions several authorities, private and public organisations have created health app assessment frameworks. However, most of them provide assessment results of no more than a few dozen apps. “The WHO compared in 2018 20 health app assessment frameworks for the EU.³ The frameworks differed a lot in topics covered, stakeholders addressed, existing frameworks referenced, and standards aligned with. A recent Nature article that compared health app policies in nine countries concluded none of them had yet succeeded in making health app assessment processes efficient.⁴ This multitude of frameworks creates an unworkable situation for app manufacturers and proves counterproductive in achieving trust, uptake and funding of health apps. Currently, the potential of health apps in sustaining health care budgets, improving quality and accessibility of health care and addressing the shortage in health care staff is heavily underutilised.

European Union policy context

THE EU'S STEPS TOWARDS A COMMON TRANSPARENT ASSESSMENT OF HEALTH APPS

- The *Green Paper on mobile health* (2014)⁵ addresses the potential benefits and risks of health apps questioning **how to verify or ensure the efficacy of health apps (e.g. certification schemes) and how to better inform end users** on the quality and safety of health apps.
- *The Communication on enabling the digital transformation of health and care in the Digital Single Market* (2018)⁶ highlights digital tools and data for citizen empowerment and person-centred care as a key priority and proposes **common principles and certification** to facilitate supply of these tools also by Small and Medium-sized Enterprises.
- The Proposal for a *Regulation on the European Health Data Space* (2022)⁷ calls for a **voluntary labelling system for wellness apps** (Article 31) and a **cascading effect in medical devices** that aim to be interoperable with Electronic Health Record systems.



WHAT IS CEN-ISO/TS 82304-2:2021?

A TECHNICAL SPECIFICATION TO HELP YOU IDENTIFY QUALITY HEALTH APPS

CEN-ISO/TS 82304-2:2021 Health software – Part 2: Health and wellness apps – Quality and reliability[®] 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) and the International Electrotechnical Commission (IEC). CEN-ISO/TS 82304-2 was published in July 2021. The Technical Specification offers a **health app quality assessment framework** and a **health app quality label**, inspired by the very effective EU energy label.

HOW DOES CEN-ISO/TS 82304-2:2021 WORK?

HEALTH APP QUALITY ASSESSMENT FRAMEWORK AND EU CERTIFICATION SCHEME

The CEN-ISO/TS 82304-2 health app quality assessment framework consists of 81 questions. Sixty-seven of these questions are score-impacting quality requirement questions. The framework was grounded in 25 existing frameworks, a Delphi study with 83 experts from eight stakeholder groups from six continents and tested for the Dutch Ministry of Health with COVID-19 symptom apps. The framework refers to 28 existing standards.

To obtain the health app quality label for a specific app, manufacturers must provide supporting evidence. This evidence will be assessed by a CEN-ISO/TS 82304-2 accredited app assessment organisation using the **EU certification scheme** ('handbook for accredited app assessors') that Label2Enable will develop.

HEALTH APP QUALITY LABEL AND REPORT

The health app quality label communicates the results of the CEN-ISO/TS 82304-2 health app assessment in one glance. It displays characteristics like name, icon, manufacturer and health benefit of the app as well as scores, ranging from a green A (best score) to a red E (worst score) in **four quality aspects**. After testing with people with limited health literacy these aspects were phrased:

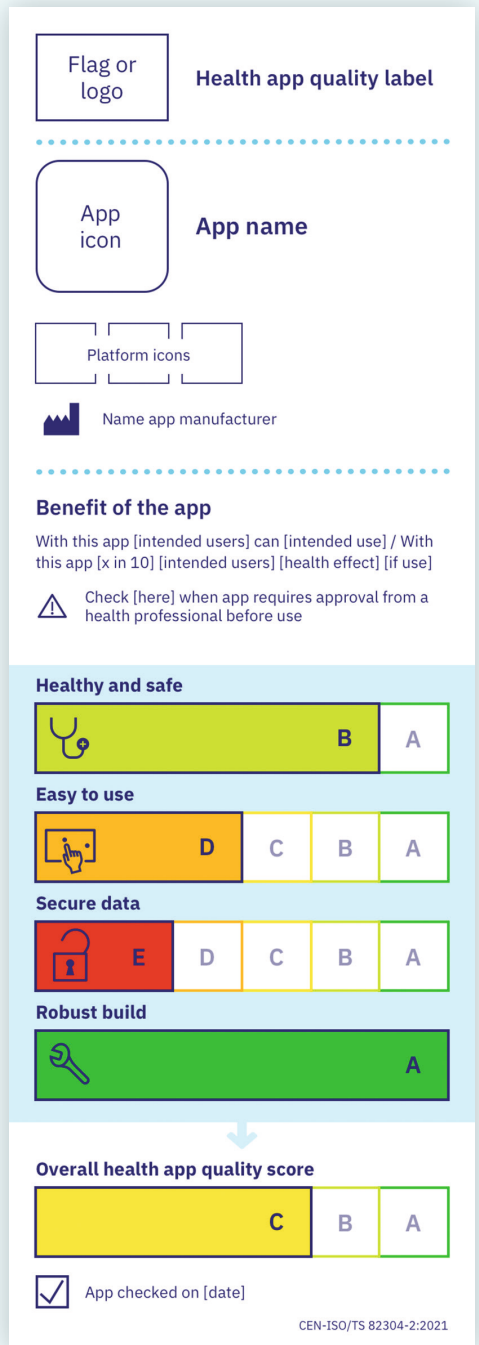
- **Healthy and safe**
- **Easy to use**
- **Secure data**
- **Robust build**

Label2Enable will translate the label in all the official commonly used European languages.

The health app quality report reveals the answers to all 81 questions of the framework in the level of detail health professionals need to recommend a health app and insurers need as a basis for reimbursement decision-making. Label2Enable will gather guidance what that level of detail is.

What is a Technical Specification?

A Technical Specification (TS) is work still under technical development. A TS is published for immediate use, but it is also a means to obtain feedback. The aim is that it will eventually be transformed and republished as an International Standard (IS).





WHO CAN BENEFIT FROM CEN-ISO/TS 82304-2:2021?

For example:

- **Patients, citizens, and carers** who seek to use health apps
- **App manufacturers** who seek to deliver quality apps
- **Health care providers, health professionals and health professional organisations** who seek to recommend or prescribe apps
- **Health and care systems and authorities** who seek to reimburse apps
- **App assessment organisations** who seek to use a trusted, globally recognised health app assessment framework
- **App stores and app libraries** who seek to help their customers make informed decisions on health apps

WHAT DOES THE LABEL2ENABLE PROJECT DO?

LABEL2ENABLE HELPS IMPLEMENT CEN-ISO/TS 82304-2:2021

Label2Enable is built on **three pillars**:

TRUST

Trust adds the missing trust elements that stakeholders require to use the label and adopt the TS. Label2Enable will co-create an **EU certification scheme** ('handbook for accredited app assessors') aligned with EU values and EU legislation (General Data Protection Regulation, Medical Device Regulation etc.). The certification scheme will be tested with six health app assessment organisations, including two notified bodies, and 24 health app manufacturers. An entity will be set up to maintain the EU certification scheme and have app assessors accredited. And the project will evaluate different business models for app assessment and explore existing label legislations to assess their applicability to the health app quality label.

USE

Label2Enable will co-create **the communication consumers and health professionals need** to consider to download and use and to recommend health apps. An intentionally diverse patient, citizen, and carer advisory group and health professional advisory group are set up to ensure the citizen and health professional centredness of project tasks. A survey for citizens and one for health professionals will explore which types of health apps are already recommended and used, thoughts on reviewing, rating and recommending apps, added value of the label, and which remaining barriers to address. We test the label in four corners of Europe with people with low health literacy to learn how to introduce the label, find out how to effectively display the label in app stores, app libraries and trusted health sources, and provide guidance on the content of the health app quality report.

ADOPTION


Trust and use promote adoption of the assessment framework and the label by health care systems and authorities, as well as app stores, app libraries and other trusted sources. Label2Enable aims to co-create a **single market** for health apps (cross-country recognition of the EU certification scheme). We will support health care systems and authorities in piloting CEN-ISO/TS 82304-2 and document these pilots in 'use stories'. With health insurers and Health Technology Assessment (HTA) bodies we will explore the potential of the TS in decision-making on reimbursement. We engage with stakeholders in many ways. Also to look five to ten years ahead what success of the TS would be to them and how to get there.

GET INVOLVED!

WOULD YOU LIKE TO LEARN MORE ABOUT THE PROJECT?

Label2Enable works at a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps. We welcome contact with stakeholders interested in using CEN-ISO/TS 82304-2 and the related health app quality label. Check out the project website for opportunities to engage with the project. To stay up to date, follow us on social media or sign up for our newsletter!




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