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!

🌐 label2enable.eu

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LABEL2 ENABLE

Easy to use — E D C B A

Secure data — D C B A

Robust build — D C B

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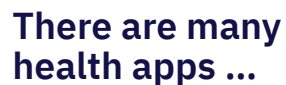   Available at: https://www.iso.org/standard/78182.html
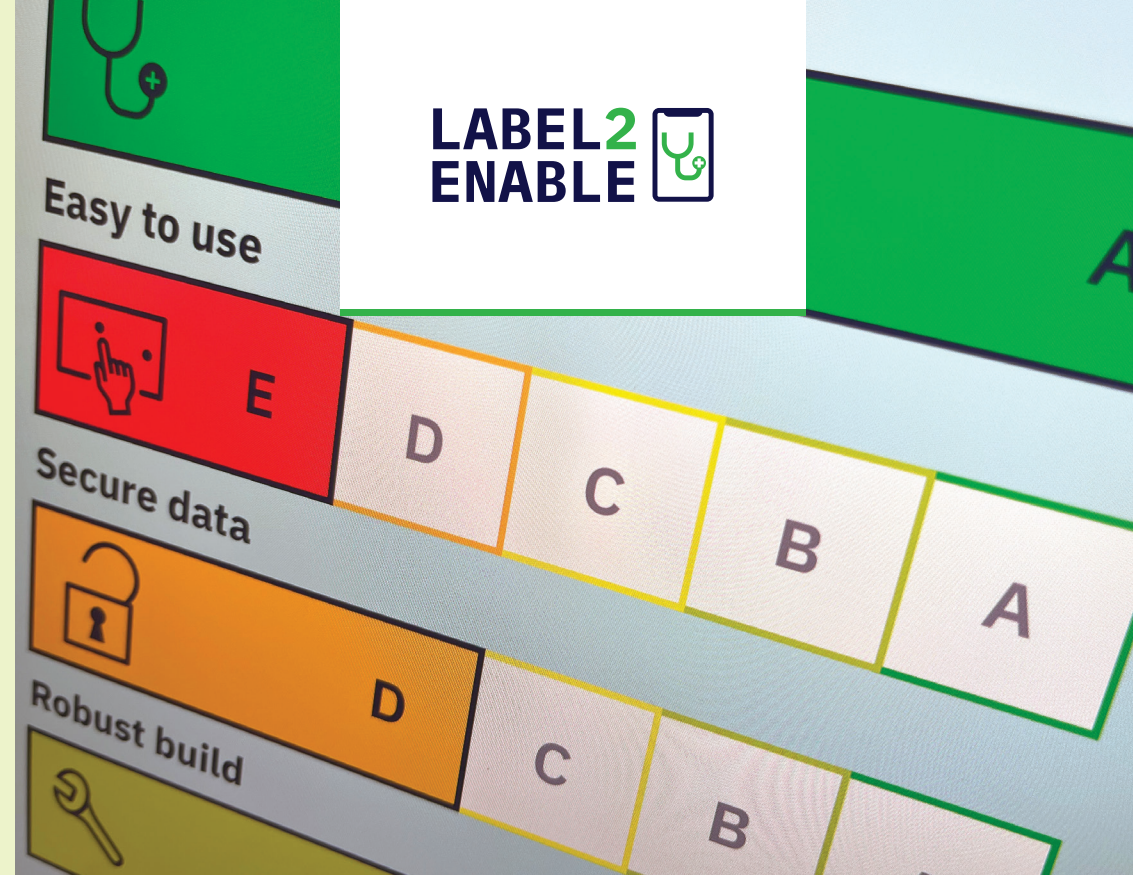
TRUST • USE • ADOPTION

Label2Enable helps implement
CEN-ISO/TS 82304-2:2021
Health and wellness apps
Quality and reliability

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.

There are many health apps ...

HEALTH APPS CAN OFFER VARIOUS BENEFITS

The use of health and wellness apps (mobile Health or mHealth, medical devices and those that are not) can empower citizens and benefit patients and carers. Health apps can for example inform them about healthy habits and choices and thus prevent or postpone chronic illnesses, help manage their disease, facilitate personalised treatment, enable better communication with health professionals, and more. On a system level, health apps can make health care more accessible, efficient and sustainable. Health apps are also welcome in the context of a shortage of health care staff, a pandemic and increasing health care costs.

OVER 350,000 HEALTH APPS

Over 350,000 consumer health apps exist worldwide. In 2020 alone, more than 90,000 such apps were introduced – an average of more than 250 apps per day. Rather than wellness management, apps increasingly focus on health condition management: 47% of all apps in 2020, up from 28% in 2015.[1]

... but picking "good" health apps is difficult

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.