

Testing health app quality labels

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EuroHealthNet Annual seminar 2026

Session 2: Promising health promotion and disease prevention initiatives in the digital era

should we steer people to evidence-based apps?

Wyatt (2018) How can clinicians, specialty societies, and others evaluate and improve the quality of apps for patient use?

Larsen et al. (2019) Using science to sell apps: Evaluation of mental health app store quality claims

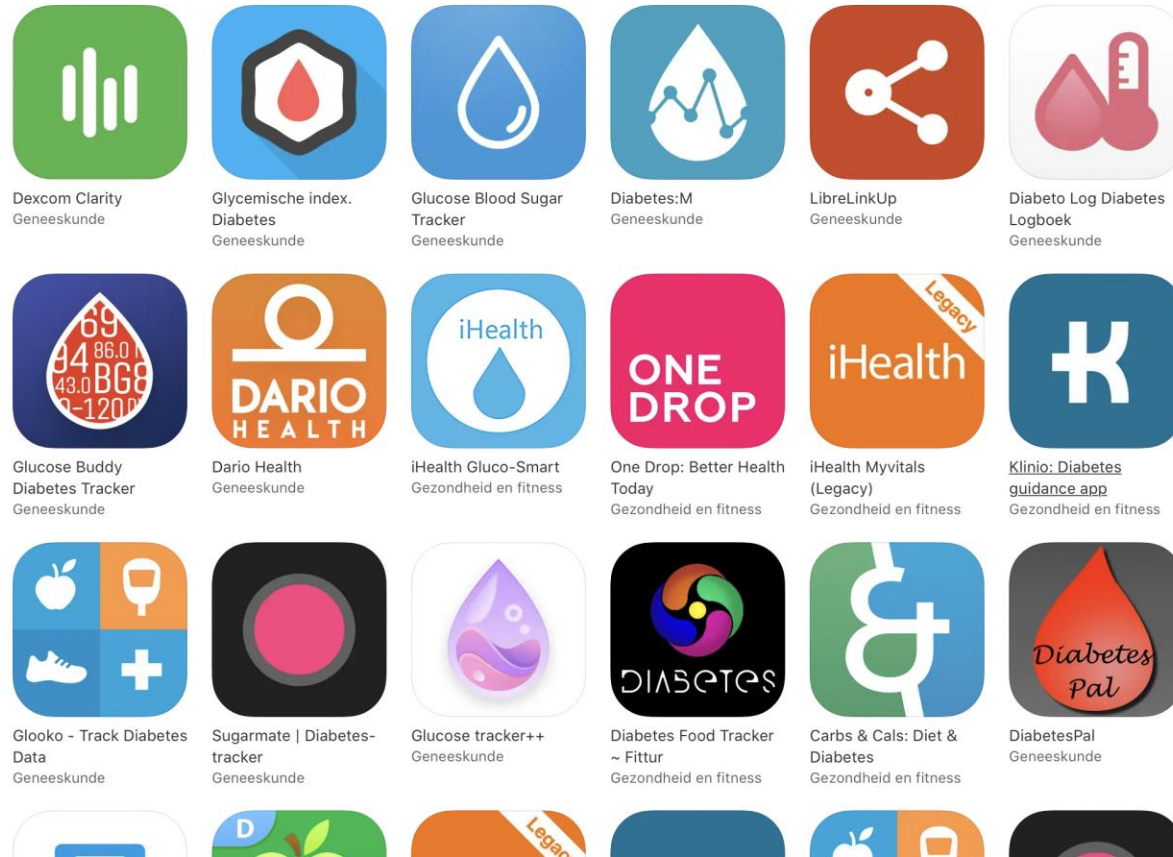
Singh et al. (2016) Many health apps target high-need, high-cost populations, but gaps remain

Hyzy et al. (2024) Don't judge a book or health app by its cover: User ratings and downloads are not linked to quality

App Store Preview

mySugr - Diabetestracker-log

Suggesties voor jou



- order of apps
 - number of downloads
 - app descriptions
 - user reviews
- are not linked to quality

so currently potential users cannot make an informed decision

should we steer people? – app benefits and risks

Digital Health and Care



TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect..

- 90% agree** To access their own health data (requiring interoperable and quality health data)
- 80% agree** To share their health data (if privacy and security are ensured)
- 80% agree** To provide feedback on quality of treatments

Support European Commission:

- 1 Secure access and exchange of health data**

Ambition: Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Actions:

 - eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
 - Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
 - Recommended exchange format for interoperability of existing electronic health records in Europe.
- 2 Health data pooled for research and personalised medicine**

Ambition: Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:

 - Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
 - Specifications for secure access and exchange of health data.
 - Pilot actions on rare diseases, infectious diseases and impact data.
- 3 Digital tools and data for citizen empowerment and person-centred healthcare**

Ambition: Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:

 - Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
 - Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
 - Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

#DigitalSingleMarket #DigitalHealth @eHealth_EU @EU_Health

Akbar et al (2020):

74 studies:

- 80 safety concerns identified (67 related to information quality, 13 to app functionality)
- 5/52 reports of actual / potential consequences had potential for patient harm
- 66 reports about gaps in app development, including lack of expert involvement, poor evidence base, and poor validation

European Commission (2018)

Communication on enabling the digital transformation of health and care in the Digital Single Market

Akbar et al. (2020) Safety concerns with consumer-facing mobile applications and their consequences: a scoping review

should we steer people? – users vs non-users

Paradis et al. (2022) Use of Smartphone Health Apps Among Patients Aged 18 to 69 Years in Primary Care: Population-Based Cross-sectional Survey

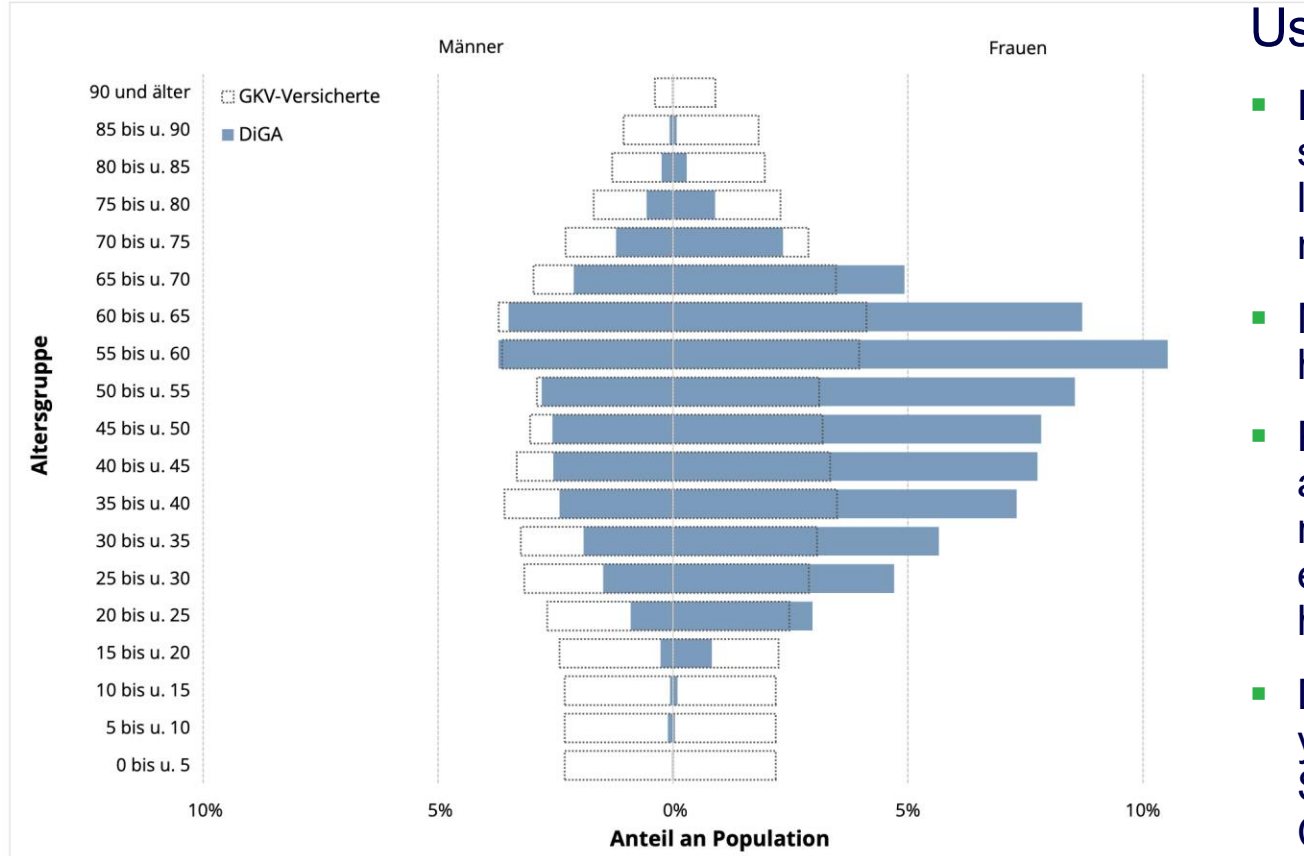
Bol et al. (2018) Differences in mobile health app use: A source of new digital inequities?

Lima et al. (2025) Acceptance of Digital Health in Portugal: An Example of Digital Divide

Causio et al. (2025) Public perceptions and engagement in mHealth: a European survey on attitudes toward health apps use and data sharing

GKV-Spitzenverband (2026) DiGA-Bericht des GKV- Spitzenverbandes 2025

Abbildung 20 Inanspruchnahme nach Alter und Geschlecht (2025)



Quelle: Daten des GKV-Spitzenverbandes gem. § 33a Abs. 6 SGB V; Datenjahr 2025; n = 694.769; amtliche KM 6-Statistik
Abbildung der Inanspruchnahme auf anonymisierter Fallebene.

Users:

- FR: < 30 years, women, in higher socio-professional category, live in larger cities – chronic conditions not associated with app use
- NL: younger, higher educated, higher e-health literacy skills
- PT: positive views of digital health and more frequent use are much more common among those more educated, richer, younger and with higher levels of health literacy
- DE, ES, FR, HU, IT, NL, PL, RO: younger age, women, Eastern / Southern Europe (compared to Central Europe), tertiary education

should we review + recommend + reimburse apps?

EU (2018) Transformation of health and care in the digital single market

WHO European Region (2023) The ongoing journey to commitment and transformation – Digital health in the WHO European Region 2023

Uncovska et al. (2023) Patient Acceptance of Prescribed and Fully Reimbursed mHealth Apps in Germany: An UTAUT2-based Online Survey Study

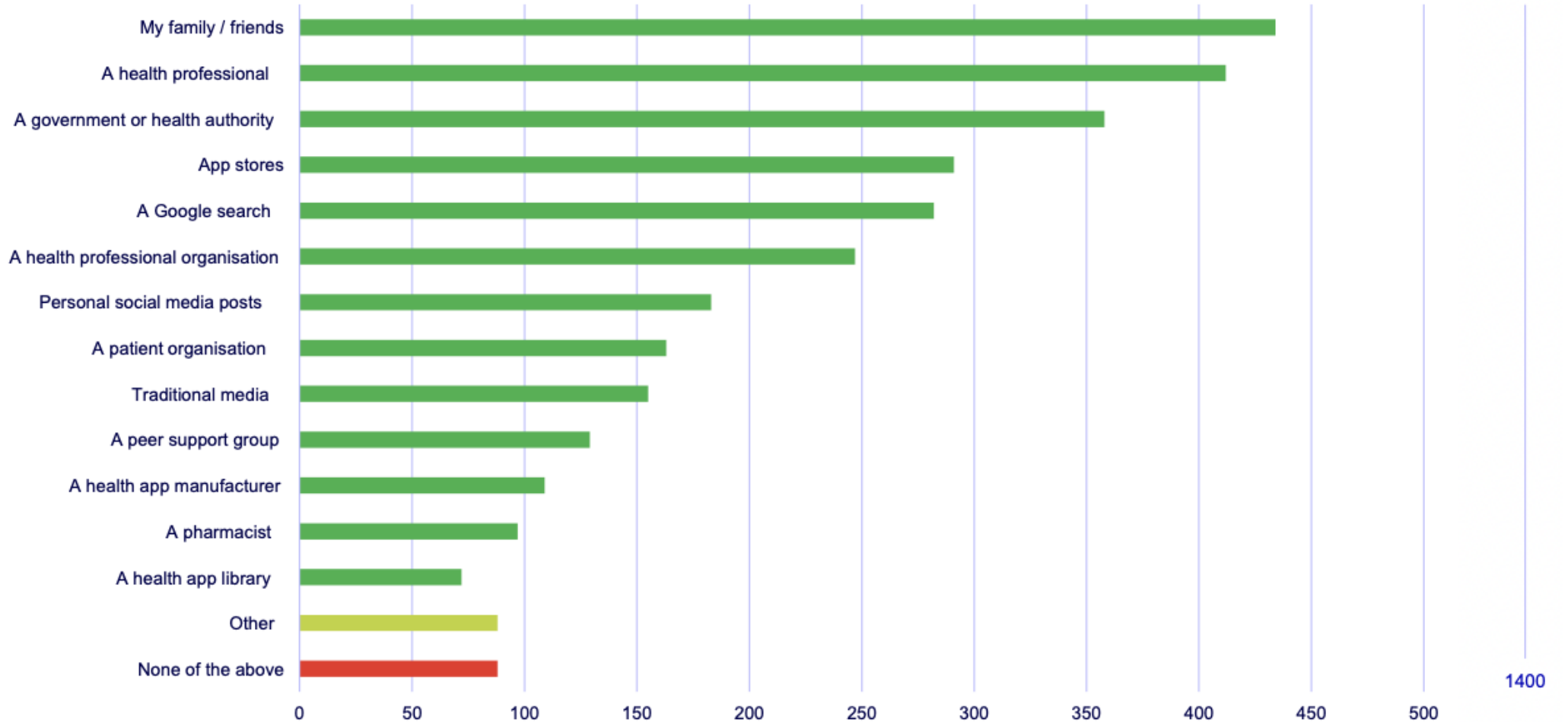
GKV-Spitzenverband (2026) DiGA-Bericht des GKV- Spitzenverbandes 2025

Wangler & Jansky (2024) How can primary care benefit from digital health applications? – a quantitative explorative survey on attitudes and experiences of general practitioners in Germany

- EU (2018): facilitate supply of innovative digital-based solutions for health, also by SMEs, using **common principles and certification**
- WHO European Region (2022): the **evaluation** of mHealth programmes and **apps should become the norm rather than the exception**
- Uncovska et al. (DE, 2023):
 - 76% willing to use health apps
 - **53% would only use health apps if quality certified by government,**
 - **33% only if prescribed by physicians** (39% average e-literacy vs 27% very high e-literacy)
 - **27% willing to pay out-of-pocket (no amount mentioned)**
- GKV-Spitzenverband (DE, 2026):
 - appr. 58% of all 496.000 DiGA prescriptions in 2025 were by GPs
- Wangler & Jansky (DE, 2024):
 - **24% of 5868 GPs trusted themselves to competently advise patients on DiGA**
 - 14% had prescribed DiGA
 - 13% planned to do so

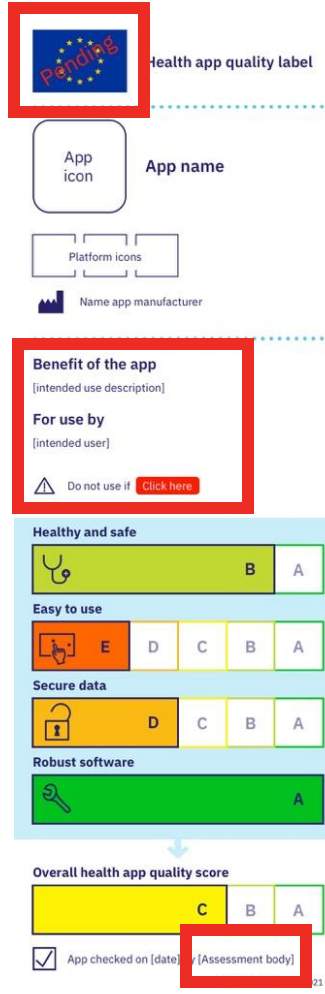
should we review + recommend apps? – citizens

1228
respondents



Shokralla et al. (2026)
Trust and use of
recommendations for
health apps among
European residents:
Cross-sectional survey

labels – do they work / are they trusted? - citizens

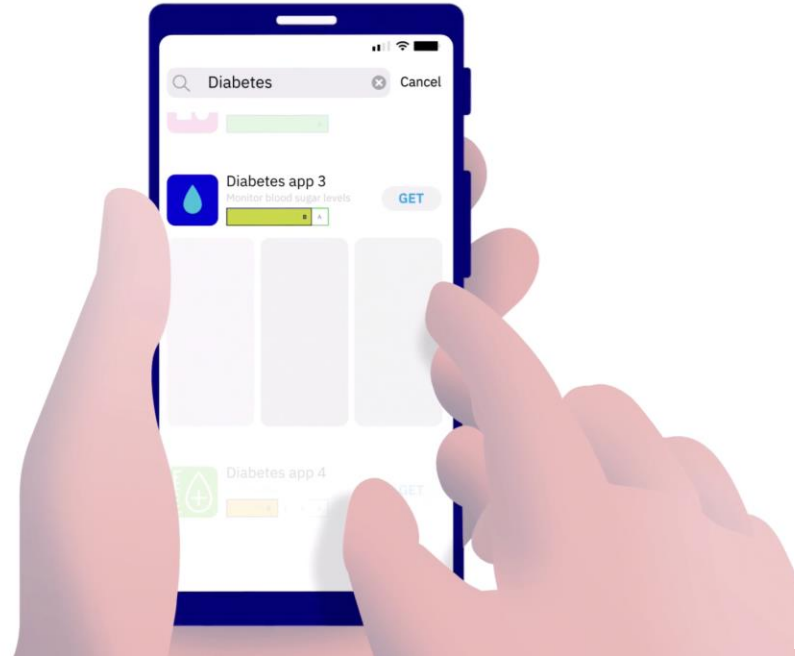


Hoogendoorn et al. (upcoming) Usability testing the CEN-ISO/TS 82304-2 health app quality label in all 4 corners of Europe

Pajor et al. (upcoming) Testing the effectiveness of an explanatory video about a health app quality label: An experimental study

<https://vimeo.com/showcase/11257693>

Adriaanse et al. (upcoming) Beyond the Stars: How Objective Quality Labels vs. Subjective Star Ratings Shape the Decision to Download Health Apps



labels – do they work / are they trusted? - doctors

Biliunaite et al. (2024)
Value of a quality label and European healthcare professionals' willingness to recommend health apps: An experimental vignette study

Caiani, Kemps, Hoogendoorn et al. (2024) Standardized assessment of evidence supporting the adoption of mobile health solutions: A Clinical Consensus Statement of the ESC Regulatory Affairs Committee

The need for ESC guidance and standardized assessment of evidence (label and report) to facilitate adoption of mobile health in clinical practice



- Patient-population, intended use, operating ranges
- Clinical validation with appropriate standards
- Reported against nominal performance
- Sufficient power and follow-up, meaningful difference
- Level of evidence
- Co-development with relevant stakeholders
- Maintenance of health information

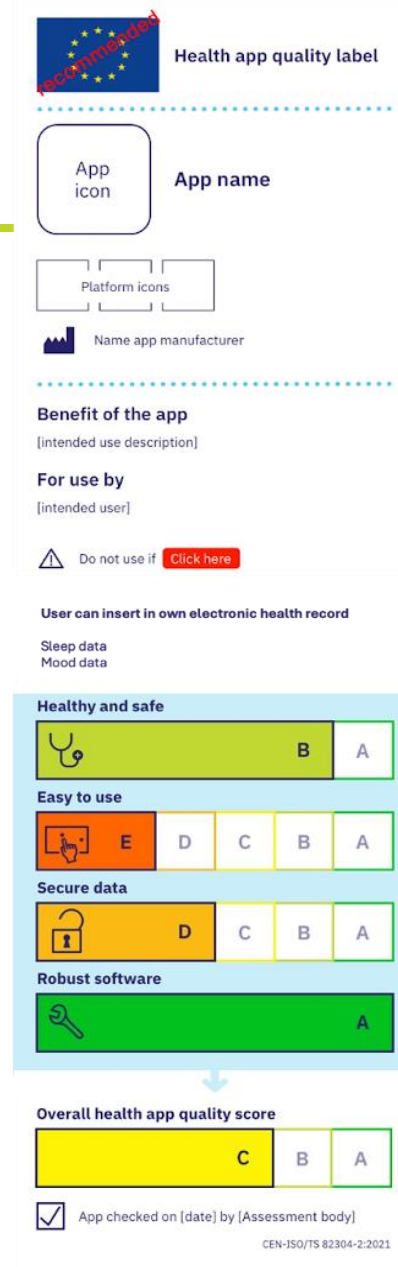


The screenshot shows a structured form for a health app quality label. It includes fields for 'Flag or logo', 'App icon', 'Platform icons', and 'Name app manufacturer'. Below these is a 'Benefit of the app' section with a warning icon and text: 'With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]'. A warning icon and text follow: 'Check [here] when app requires approval from a health professional before use'. The main body contains five categories with corresponding icons and letter grades: 'Healthy and safe' (green icon, B, A), 'Easy to use' (red icon, E, D, C, B, A), 'Secure data' (yellow icon, C, B, A), 'Robust build' (green icon, A), and 'Overall health app quality score' (yellow icon, C, B, A). At the bottom, there is a checkbox 'App checked on [date]' and a small reference code 'ESC-DS/TS/82304-2/2021'.

appetite EU regulation?

Proposal to benefit from existing evidence without eroding trust:

- **abbreviated label on EU level** (EHDS Article 47(1), self-declaration, at the right: N.B. only wellness apps for which interoperability with an EHR system is claimed, focus on interoperability and security)
- **full label on member state level** (EHDS Recital 50, third-party assessment, at the left: harmonization with ISO 82304-2)



Health app quality label

App icon App name

Platform icons

Name app manufacturer

Benefit of the app
[intended use description]

For use by
[intended user]

⚠ Do not use if [Click here](#)

User can insert in own electronic health record

Sleep data
Mood data

Healthy and safe

	B	A
--	---	---

Easy to use

	E	D	C	B	A
--	---	---	---	---	---

Secure data

	D	C	B	A
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Robust software

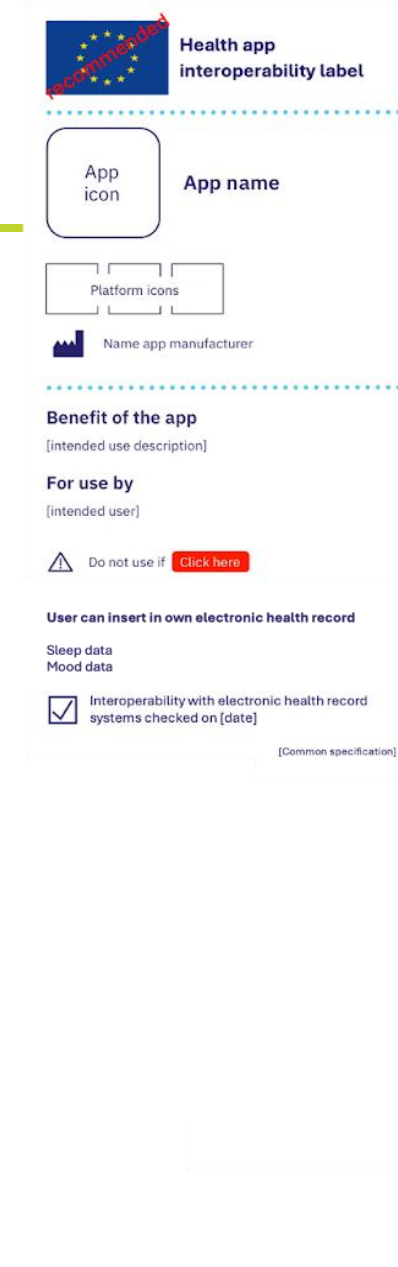
	A
--	---

Overall health app quality score

C	B	A
---	---	---

App checked on [date] by [Assessment body]

CEN-ISO/TS 82304-2:2021



Health app interoperability label

App icon App name

Platform icons

Name app manufacturer

Benefit of the app
[intended use description]

For use by
[intended user]

⚠ Do not use if [Click here](#)

User can insert in own electronic health record

Sleep data
Mood data

Interoperability with electronic health record systems checked on [date]

[Common specification]

next steps

Adoption decision-making support

Label2Scale proposal (HORIZON-HLTH-2026-01-IND-03) builds on Label2Enable multi-stakeholder roadmap to the preferred future and includes WP for citizens which explores equitable:

- app recommendations
- label positioning in app store context
- repositories
- national marketing strategies (DE: manufacturers, NL: insurer / GP workflow, NO: authority)

https://label2enable.eu/assets/downloads/label2enable_preferred-future-health-and-care-visual-1716569529.pdf

<https://diga.bfarm.de/de/verzeichnisse>

<https://digizo.nu/proceszoek/er/>

<https://tjenester.helsenorge.no/verktoy>

<https://www.youtube.com/watch?v=MhQxDz7-2J0>

