SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 82304-2:2021

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Programska oprema v zdravstvu - 2. del: Aplikacije za zdravje in dobro počutje (wellness) - Kakovost in zanesljivost (ISO/TS 82304-2:2021)

Health software - Part 2: Health and wellness apps - Quality and reliability (ISO/TS 82304-2:2021)

Gesundheits- und Wellness-Apps - Qualitätskriterien während des gesamten Lebenszyklus - Verhaltenskodex (ISO/TS 82304-2:2021)

Logiciels de santé - Partie 2: Applications de santé et de bien-être - Critères de qualité tout au long du cycle de vie - Code de pratique (ISO/TS 82304-2:2021)

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ICS:

35.080	Programska oprema	Software
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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CEN ISO/TS 82304-2

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Health software - Part 2: Health and wellness apps - Quality and reliability (ISO/TS 82304-2:2021)

Logiciels de santé - Partie 2: Applications de santé et de bien-être - Critères de qualité tout au long du cycle de vie - Code de pratique (ISO/TS 82304-2:2021)

Gesundheits- und Wellness-Apps - Qualitätskriterien während des gesamten Lebenszyklus - Verhaltenskodex (ISO/TS 82304-2:2021)

This Technical Specification (CEN/TS) was approved by CEN on 28 June 2021 for provisional application.

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European foreword

This document (CEN ISO/TS 82304-2:2021) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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Endorsement notice

The text of ISO/TS 82304-2:2021 has been approved by CEN as CEN ISO/TS 82304-2:2021 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 82304-2

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Health software —

Part 2: Health and wellness apps—Quality and reliability

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62A, *Common aspects of electrical equipment used in medical practice*, and with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 82304 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Context

Health and wellness apps are a fast-growing market, and there are now hundreds of thousands, with the most popular of these having many millions of downloads each. Some of these apps fall under medical devices regulations, most do not. These apps are often promoted directly to consumers through app stores without going through any formal evaluation. The apps often collect sensitive personal information yet do not have appropriate privacy controls, and provide advice on topics such as fertility, diet or activity that are not supported by any evidence. There are widespread concerns about the risks involved. At the same time, health apps that have proven to be effective and add to quality of life and even length of life, are not necessarily adopted at scale and reimbursed.

Many health organizations have projects to evaluate, endorse and procure apps that meet locally defined requirements. These activities are important for any app manufacturer who want to promote or sell their product to or through providers of health and wellness services, as providers want the reassurance that the apps they recommend to patients will be safe, reliable and effective. However, the cost of responding to different extensive sets of criteria and different evaluation regimes in each country, organization, or region is a barrier for app manufacturers wanting to make their products available in multiple markets. It is also a problem for those evaluating apps and maintaining libraries of health and wellness apps. They can miss out on products that effectively address health issues and health system inefficiencies, do not benefit from economies of scale of others evaluating the same apps and different evaluations can contradict one another, causing further confusion instead of trust. Because of the time investment involved, the vast majority of apps are not evaluated at all, although top 10 lists suggest otherwise.

There are several International Standards on health software related to product safety and lifecycle processes that are applicable to all health software, including health apps. This document provides quality requirements and health app quality labels as ways for app manufacturers and app assessment organizations to communicate the quality and reliability of health apps.

The working practice within app development is to deliver a focused piece of functionality, building on an existing platform - often with a small team doing the work who can be unfamiliar with health software development. This document includes Annex D to provide guidance specific to this community.

A vibrant transparent market for health apps will benefit individuals and programs across the world that are addressing issues such as aging population, unhealthy lifestyles, chronic diseases, affordability of or constrained budgets for health and care, unequal quality and access to health services, and shortages in health professionals.

This document makes no attempt to determine whether a health app is or should be regulated.

Development methodology

The quality requirements (Clause 5) and health app quality score calculation method (Annex B) have been developed with a Delphi consensus study. Further input was gathered with surveys, interviews, and review of existing standards and health app assessment frameworks. The health app quality label (Annex A) has been inspired by the EU energy label that is also used in more than 50 countries outside Europe, the Nutriscore and the FDA over-the-counter medicine label. Think-aloud testing of the health app quality label with people with low health literacy in the Netherlands and subsequently Egypt and Mexico was used to ensure adequate understanding in different contexts.

Outline

This document defines a set of questions and supporting evidence that can be used to clarify the quality and reliability of a health app. A health app quality label is defined to summarize this information in a visually appealing way.

The questions and evidence are listed under the following headings taking into account the need to be understood by those with low health literacy:

— Product information;

— Healthy and safe;

— Easy to use;

— Secure data;

— Robust build.

This document provides requirements for the specification for the health app quality label in Annex A, and a calculation method in Annex B to generate the quality score information that is displayed on the label.

This document also contains annexes covering the following:

— Annex C: the rationale for the scope of this document and content;

— Annex D: a walk through the relevant international health software products and process standards, providing recommendations and explanations, where appropriate, to help those developing or evaluating health and wellness apps to understand how the standards can be applied;

— Annex E: an example of how a profile of this document can be defined for the assessment of contact tracing apps. Similar profiles can be produced for other specific use cases;

— Annex F: ethical considerations for app manufacturers and evaluators to take into account;

— Annex G: a range of ways that this document can be used by different stakeholders throughout the lifecycle of a health app.

Health software —

Part 2:
Health and wellness apps—Quality and reliability

1 Scope

This document provides quality requirements for health apps and defines a health app quality label in order to visualize the quality and reliability of health apps.

This document is applicable to health apps, which are a special form of health software. It covers the entire life cycle of health apps.

This document is intended for use by app manufacturers as well as app assessment organizations in order to communicate the quality and reliability of a health app. Consumers, patients, carers, health care professionals and their organizations, health authorities, health insurers and the wider public can use the health app quality label and report when recommending or selecting a health app for use, or for adoption in care guidelines, care pathways and care contracts.

NOTE 1 Health apps can be subject to national legislation, such as for medical devices.

NOTE 2 See Annex C for additional details on the scope.

Outside the scope of this document are guidelines to comply to the medical device regulation.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1 General terms

3.1.1
accessibility
extent to which products, systems, services, environments and facilities can be used by people from a population with the widest range of user needs, characteristics and capabilities to achieve identified goals in identified contexts of use

Note 1 to entry: Context of use includes direct use or use supported by assistive technologies.

[SOURCE: ISO 9241-11:2018, 3.2.2]

3.1.2
effectiveness
ability to produce the intended result

[SOURCE: ISO 81001-1:2021, 3.2.5]

3.1.3
efficiency
resources used in relation to the results achieved

Note 1 to entry: Typical resources include time, human effort, costs and materials.

[SOURCE: ISO 9241-11:2018, 3.1.13]

3.1.4
evidence
directly measurable characteristics of a process and/or product that represent objective, demonstrable proof that a specific activity satisfied a specified requirement

[SOURCE: ISO/IEC 21827:2008, 3.19]

3.1.5
health
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[SOURCE: WHO 1948[53]]

3.1.6
health benefit
positive impact or desirable outcome of the use of health software on the health of an individual

3.1.7
health intervention
act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions

[SOURCE: WHO 1948[53]]

3.1.8
health issue
representation of an issue related to the health of a subject of care as identified by one or more healthcare actors

Note 1 to entry: According to this definition, a health issue can correspond to a health problem, a disease, an illness or another kind of health condition.

EXAMPLE A loss of weight, a heart attack, a drug addiction, an injury, dermatitis.

[SOURCE: ISO 13940:2015]

3.1.9
health need
deficit in the current health state compared to aspects of a desired future health state

[SOURCE: ISO 13940:2015]

3.1.10
intended use
intended purpose
health-related use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended health benefit, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

Note 2 to entry: A health app has an intended use irrespective of whether it is a medical device. A concept of "intended use" is used in a more restrictive sense in some medical device regulations.

[SOURCE: ISO/IEC Guide 63:2019, 3.4, modified — Note 2 to entry added, "intended purpose added" as a preferred term.]

3.1.11
intended users
group(s) of people for whom a product is designed

Note 1 to entry: In many cases the actual user population is different from that originally intended by the manufacturer. The intended user group is based on realistic estimations of who the actual users of the product will be.

[SOURCE: ISO 20282-1:2006, 3.12]

3.1.12
interoperability

ability of two or more systems or components to exchange information and to use the information that has been exchanged

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

3.1.13
joint PII controller
PII controller that determines the purposes and means of the processing of PII jointly with one or more other PII controllers

[SOURCE: ISO/IEC 27701:2019, 3.1]

3.1.14
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one of more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information by means of in vitro examination of specimens derived from the human body,