Teknisk specifikation
SIS-CEN ISO/TS 82304-2:2021

Programvara för hälsoappar –
Del 2: Kvalitet och tillförlitlighet (ISO/TS 82304-2:2021)

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

Svenska Institutet för Standarder

Språk: engelska/English
Utgåva: 1

Denna standard är såld av
SEK Svensk Elstandard som även lämnar
allmänna upplysningar om svensk och utländsk standard.
Postadress: SEK, Box 1284, 164 29 Kista
Telefon: 08-444 14 00.
E-post: sek@elstandard.se Internet: www.elstandard.se

Svenska Institutet för Standarder

Det här dokumentet kan hjälpa dig att effektivisera och kvalitetssäkra ditt arbete. SIS har fler tjänster att erbjuda dig för att underlätta tillämpningen av standardiseringsprodukter i din verksamhet.

SIS Abonnemang
Snabb och enkel åtkomst till gällande standardiseringsprodukt med SIS Abonnemang, en prenumerationstjänst genom vilken din organisation får tillgång till all världens standardiseringsprodukter, senaste uppdateringarna och där hela din organisation kan ta del av innehållet i prenumerationen.

Utbildning, event och publikationer
Vi erbjuder även utbildningar, rådgivning och event kring våra mest sålda standardiseringsprodukter och frågor kopplade till utveckling av standardiseringsprodukter. Vi ger också ut handböcker som underlättar ditt arbete med att använda en specifik standardiseringsprodukt.

Vill du delta i ett standardiseringsprojekt?
Genom att delta som expert i någon av SIS 300 tekniska kommittéer inom CEN (europeisk standardisering) och/eller ISO (internationell standardisering) har du möjlighet att påverka standardiseringsarbetet i frågor som är viktiga för din organisation. Välkommen att kontakta SIS för att få veta mer!

Kontakt
Skriv till kundservice@sis.se, besök sis.se eller ring 08 - 555 523 10

Upplysningar om sakinnehållet i standardiseringsprodukten lämnas av Svenska institutet för standarder, telefon 08 - 555 520 00. Standardiseringsprodukter kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standardiseringsprodukt.

Dokumentet är framtaget av kommittén för Hälso- och sjukvårdsinformatik, SIS/TK 334.

Har du synpunkter på innehållet i den här standardiseringsprodukten, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standardiseringsprodukter inom området? Gå in på www.sis.se - där hittar du mer information.

Fastställd: 2021-08-16
ICS: 35.080;35.240.80

Svenska Institutet för Standarder

Denna tekniska specifikation är inte en svensk standard. Detta dokument innehåller den engelska språkversionen av CEN ISO/TS 82304-2:2021.

This Technical Specification is not a Swedish Standard. This document contains the English language version of CEN ISO/TS 82304-2:2021.

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 82304-2

August 2021

ICS 35.080; 35.240.80

English Version

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.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. CEN ISO/TS 82304-2:2021 E

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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.

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.