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BSI Standards Publication

Health software

Part 2: Health and wellness apps – Quality and reliability

bsi.

National foreword

This Published Document is the UK implementation of CEN ISO/TS 82304-2:2021. It is identical to ISO/TS 82304-2:2021.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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European foreword

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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.

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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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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).

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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.

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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.

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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]

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