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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# Contents

Page

# Foreword

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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).



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,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

Note 1 to entry: Products that can be considered to be medical devices in some jurisdictions but not in others include

— disinfection substances,

— aids for persons with disabilities,

— devices incorporating animal and/or human tissues, and

— devices for in-vitro fertilization or assisted reproductive technologies.

[SOURCE: ISO/IEC Guide 63:2019, 3.7]

**3.1.15**
**personally identifiable information**
**PII**
any information that (a) can be used to establish a link between the information and the natural person to whom such information relates, or (b) is or can be directly or indirectly linked to a natural person

[SOURCE: ISO/IEC 29100:2011/Amd.1:2018, 2.9, modified — Note to entry removed.]

**3.1.16**
**privacy**
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual



[SOURCE: ISO/TS 27790:2009, 3.56]

**3.1.17**
**processing of PII**
operation or set of operations performed upon Personally Identifiable Information (PII)



Note 1 to entry: Examples of processing operations of PII include, but are not limited to, the collection, storage, alteration, retrieval, consultation, disclosure, anonymization, pseudonymization, dissemination or otherwise making available, deletion or destruction of PII.

[SOURCE: ISO/IEC 29100:2011, 2.23]

**3.1.18**
**quality**
degree to which a set of inherent characteristics of an object fulfils requirements

[SOURCE: ISO 9000:2015, 3.6.2, modified — Notes to entry removed.]

**3.1.19**
**reliability**
ability of a device or a system to perform its intended function under given conditions of use for a specified period of time or number of cycles

[SOURCE: ISO 14907-1:2020, 3.23]

**3.1.20**
**safety**
freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 63:2019, 3.16]

**3.1.21**
**satisfaction**
extent to which the user's physical, cognitive and emotional responses that result from the use of a system, product or service meet the user's needs and expectations

Note 1 to entry: Satisfaction includes the extent to which the user experience that results from actual use meets the user's needs and expectations.

Note 2 to entry: Anticipated use can influence satisfaction with actual use.

[SOURCE: ISO 9241-11:2018, 3.1.14]

**3.1.22**
**security**
condition that results from the establishment and maintenance of protective measures that ensure a state of inviolability from hostile acts or influences

Note 1 to entry: Hostile acts or influences could be intentional or unintentional.

**3.1.23**
**usability**
extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use

[SOURCE: ISO 9241-210:2019, 3.13]

**3.1.24**
**user**
person who interacts with a system, product or service



Note 1 to entry: Users of a system, product or service include people who operate the system, people who make use of the output of the system and people who support the system (including providing maintenance and training).



[SOURCE: ISO 9241-11:2018, 3.1.7]

**3.1.25**
**use error**
reasonably foreseeable misuse

## 3.2 Terms relating to apps

**3.2.1**
**app**
software application that can be executed (run) on a computing platform

Note 1 to entry: Apps were initially established as a category of software developed to run on mobile platforms for a single or limited number of purposes. However, the distinction between apps and other software applications has become less clear as a wider range of computing platforms are marketed as supporting apps and app repositories, and as apps with a wider range of functions are developed.

Note 2 to entry: An example is a software application running on a handheld commercial off-the shelf computing platform, with or without wireless connectivity, or a web-based software application that is tailored to a mobile platform but is executed on a server.

[SOURCE: BS PAS 277:2015, 3.1.1, modified — 'and is typically a small application run or accessed on mobile devices' removed from the definition, Note 2 to entry modified.]

**3.2.2**
**app assessment organization**
organization that evaluates apps

Note 1 to entry: This can be done to inform the purchasing or recommendation of an app, or as part of a certification program.

**3.2.3**
**health app**
**health and wellness app**
app intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

[SOURCE: IEC 82304-1:2016 3.6, modified — Changed 'software' to 'app' in term and definition, 'health and wellness app' was added as a term, notes to entry deleted.]

**3.2.4**
**health software**
software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

Note 1 to entry: Health software fully includes what is considered software as a medical device.

Note 2 to entry: The scope of IEC 82304-1 refers to the subset of health software that is intended to run on general computing platforms.

[SOURCE: IEC 82304-1:2016, 3.6]



**3.2.5**
**health software product**
combination of health software and accompanying documentation



[SOURCE: IEC 82304-1:2016, 3.7, modified — 'documents' changed to 'documentation'.]

**3.2.6**
**manufacturer**
**app manufacturer**
natural or legal person with responsibility for design and/or manufacture of a health app with the intention of making the health app available for use, under their own name; whether or not such a health app is designed and/or manufactured by that natural or legal person themselves or on their behalf by (an)other natural or legal person(s)

Note 1 to entry: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the health app in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority within that jurisdiction.

Note 2 to entry: 'Design and/or manufacture' can include specification development, production, assembly, processing, packaging, repackaging, labelling, relabelling, installation, or remanufacturing of a health app, or putting a collection of apps, and possibly other products, together for a health purpose.

Note 3 to entry: Any natural or legal person who assembles or adapts a health app that has already been supplied by another person for an individual subject of care or wellbeing, in accordance with the instructions for use, is not the app manufacturer, provided the assembly or adaptation does not change the intended use of the health app.

Note 4 to entry: Any natural or legal person who changes the intended use of, or modifies, a health app without acting on behalf of the original app manufacturer and who makes it available for use under their own name, should be considered the app manufacturer of the modified health app.

Note 5 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the health app or the packaging, without covering or changing the existing labelling, is not considered an app manufacturer.

 

[SOURCE: ISO/IEC Guide 63:2019, 3.6, modified — 'medical device' replaced with 'health app', 'app manufacturer' was added as a term, Notes 2 and 7 to entry deleted.]

**3.2.7**
**session management**
process of securing repeated access of a user to the health app, once authentication has been established, e.g. automatic logout after a certain time of inactivity

**3.2.8**
**validation**
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for validation are sometimes called a qualification process.

Note 3 to entry: The word "validated" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.13, modified — Notes 2 and 3 to entry have been changed.]

**3.2.9**
**verification**
confirmation through the provision of objective evidence, that specified requirements have been fulfilled



Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.



Note 3 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

## 3.3 Terms relating to risk management

**3.3.1**
**authentication**
process of validating a user or process to verify that the user or process is not a counterfeit

Note 1 to entry: Methods to validate the identity of the user of a health app may include password, Face ID, Touch ID, Oauth2.

[SOURCE: ISO/IEC/IEEE 9945:2009+Cor 1:2013+Cor 2:2017, 3.31, modified — Note to entry added.]

**3.3.2**
**authorization**
process of verifying that a user or process has permission to use a resource in the manner requested

Note 1 to entry: To ensure security, the user or process would also need to be authenticated before granting access

[SOURCE: ISO/IEC/IEEE 9945:2009+Cor 1:2013+Cor 2:2017, 3.32, modified — Second sentence in the definition changed to Note to entry.]

**3.3.3**
**harm**
injury or damage to the health of people or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

**3.3.4**
**hazard**
potential source of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

**3.3.5**
**risk**
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

**3.3.6**
**risk analysis**
systematic use of available information to identify hazards and to estimate the risk

[SOURCE: ISO/IEC Guide 51:2014, 3.10]

**3.3.7**
**risk control**
process in which decisions are made and measures implemented by which risks are reduced to, and maintained within, specified levels

[SOURCE: ISO/IEC Guide 63: 2019, 3.12]

**3.3.8**
**residual risk**
risk remaining after risk control measures have been implemented

[SOURCE: ISO/IEC Guide 63: 2019, 3.9]



# 4 Health app assessment process

## 4.1 Quality assessment

The health app manufacturer shall provide answers to the questions defined in Clause 5 in order to conform with this document. The evidence defined in Clause 5 for each question is provided by the health app manufacturer to an app assessment organization.

Where the health app is available on different platforms and the answers to the questions defined in Clause 5 are not the same for each platform, then a separate set of answers shall be provided for the health app for each platform.

Annex G describes potential uses of this document for stakeholders including app assessment organizations.

## 4.2 Quality requirements

The quality requirement questions in Clause 5 are grouped under five sections, with 'Product information' and four aspects of quality:

— Healthy and safe;

— Easy to use;

— Secure data;

— Robust build.

The questions have different purposes that are indicated using the subheading 'PURPOSE':

— Label content: Question to capture information to be provided in the health app quality label. The answer does not impact the health app score;

— Requirements level: Question to establish which subsequent questions are to be asked;

— Colour coding: Question to establish a quality and reliability aspect of the health app. The answer affects the health app score (in Annex B) and colour in a particular quality aspect on the health app quality label (in Annex A). The colour coding questions shall be answered with 'Yes' or 'No' or, in some cases, 'Not applicable'. This way, the answers can be used to derive scores for the health app quality label;

— Filtering: Question to help app repository users to search and filter for relevant apps in a consistent way. The answer does not impact the health app score;

— App assessment: Questions to enable app evaluation. The response is provided to the app assessment organization only.

### 4.3 Health app quality report

The set of answers to the 'Label content', 'Requirements level', 'Colour coding' and 'Filtering' questions, excluding evidence provided to enable app assessment, form the health app quality report.

The health app quality report can be made available to potential customers and users of the health app to enable informed decision making.



### 4.4 Health app quality evidence pack

The health app quality evidence pack is the set of evidence as specified in Clause 5 that shall be made available to health app assessment organizations to enable the assessment process.



### 4.5 Health app quality label

The health app quality label enables consumers, patients, carers, health professionals, payers such as health insurers and health authorities to make informed decisions. The health app quality label enhances transparency concerning the quality and reliability of a health app.

The health app quality label is unrelated to any labelling requirements for medical devices.

The health app quality label shall conform to the requirements documented in Annex A, using quality scores calculated using the method defined in Annex B.

## 5 Quality requirements

### 5.1 Product information

#### 5.1.1 Product

##### 5.1.1.1 Which operating systems or platforms does the health app support?

PURPOSE: Label content, Filtering