

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

Contents	Page
European foreword.....	3

## 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.

---

---

**Health software —**

**Part 2:**

**Health and wellness apps—Quality  
and reliability**





## **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
3.1 General terms .....	1
3.2 Terms relating to apps .....	5
3.3 Terms relating to risk management .....	7
<b>4 Health app assessment process</b> .....	<b>8</b>
4.1 Quality assessment .....	8
4.2 Quality requirements .....	8
4.3 Health app quality report .....	9
4.4 Health app quality evidence pack .....	9
4.5 Health app quality label .....	9
<b>5 Quality requirements</b> .....	<b>9</b>
5.1 Product information .....	9
5.1.1 Product .....	9
5.1.2 App manufacturer .....	10
5.2 Healthy and safe .....	11
5.2.1 Health requirements .....	11
5.2.2 Health risks .....	14
5.2.3 Ethics .....	17
5.2.4 Health benefit .....	18
5.2.5 Societal benefit .....	23
5.3 Easy to use .....	24
5.3.1 Accessibility .....	24
5.3.2 Usability .....	26
5.4 Secure data .....	30
5.4.1 Privacy .....	30
5.4.2 Security .....	36
5.5 Robust build .....	42
5.5.1 Technical robustness .....	42
5.5.2 Interoperability .....	45
<b>Annex A (normative) Health app quality label</b> .....	<b>47</b>
<b>Annex B (normative) Health app quality score calculation method</b> .....	<b>54</b>
<b>Annex C (informative) Rationale</b> .....	<b>58</b>
<b>Annex D (informative) Product safety and lifecycle process recommendations</b> .....	<b>59</b>
<b>Annex E (informative) Application profile – Contact tracing apps</b> .....	<b>67</b>
<b>Annex F (informative) Ethical considerations in health apps</b> .....	<b>70</b>
<b>Annex G (informative) Potential uses of this document</b> .....	<b>73</b>
<b>Bibliography</b> .....	<b>75</b>

## 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](http://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](http://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](http://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](http://www.iso.org/members.html).