

PREVIEW – content page
CEN-ISO/TS 82304-2:2021

Health Software — Part 2 Health and wellness apps - Quality and reliability

Contents

Foreword	Error! Bookmark not defined.
Introduction	Error! Bookmark not defined.
1 Scope	Error! Bookmark not defined.
2 Normative references	Error! Bookmark not defined.
3 Terms and definitions	Error! Bookmark not defined.
3.1 General terms	Error! Bookmark not defined.
3.2 Terms relating to apps	Error! Bookmark not defined.
3.3 Terms relating to risk management	Error! Bookmark not defined.
4 Health app assessment process	Error! Bookmark not defined.
4.1 Conformity assessment	Error! Bookmark not defined.
4.2 Quality requirements	Error! Bookmark not defined.
4.3 Health app quality report	Error! Bookmark not defined.
4.4 Health app quality evidence pack	Error! Bookmark not defined.
4.5 Health app quality label	Error! Bookmark not defined.
5 Quality requirements	Error! Bookmark not defined.
5.1 Product information	Error! Bookmark not defined.
5.1.1 Product	Error! Bookmark not defined.
5.1.2 App manufacturer	Error! Bookmark not defined.
5.2 Healthy and safe	Error! Bookmark not defined.
5.2.1 Health requirements	Error! Bookmark not defined.
5.2.2 Health risks	Error! Bookmark not defined.
5.2.3 Ethics	Error! Bookmark not defined.
5.2.4 Health benefit	Error! Bookmark not defined.
5.2.5 Societal benefit	Error! Bookmark not defined.
5.3 Easy to use	Error! Bookmark not defined.
5.3.1 Accessibility	Error! Bookmark not defined.
5.3.2 Usability	Error! Bookmark not defined.
5.4 Secure data	Error! Bookmark not defined.
5.4.1 Privacy	Error! Bookmark not defined.
5.4.2 Security	Error! Bookmark not defined.
5.5 Robust build	Error! Bookmark not defined.
5.5.1 Technical robustness	Error! Bookmark not defined.
5.5.2 Interoperability	Error! Bookmark not defined.
Annex A (normative) Health app quality label	Error! Bookmark not defined.
Annex B (normative) Health app quality score calculation method	Error! Bookmark not defined.
Annex C (informative) Rationale	Error! Bookmark not defined.
Annex D (informative) Product safety and lifecycle process recommendations .	Error! Bookmark not defined.
Annex E (informative) Application profile – Contact tracing apps .	Error! Bookmark not defined.

Annex F (informative) Ethical considerations in health appsError! Bookmark not defined.

Annex G (informative) Potential uses of this document.....Error! Bookmark not defined.

BibliographyError! Bookmark not defined.