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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 42984.1-2023

Health software - Part 1: General requirements for product safety

Issued on: September 7, 2023 **Implemented on: October 1, 2024**

Issued by: State Administration for Market Regulation, China National Standardization Administration

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1.Structure and Drafting Rules of Standardization Documents"

Drafting.

This document is Part 1 of GB/T 42984 "Health Software". GB/T 42984 has released the following parts.

---Part 1.General requirements for product safety.

This document is modified to adopt IEC 82304-1.2016 "Health Software Part 1.General Requirements for Product Safety".

The technical differences between this document and IEC 82304-1.2016 and their reasons are as follows.

---Replaced IEC 62304.2006 and IEC 62304.2006/AMD1 with normatively cited YY/T 0664-2020.

In.2015, the degree of consistency between the two documents was modified to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

---Replaced the IEC 60601/IEC 80601 series with the informative GB 9706 series;

---Replaced the IEC 61010 series with the informative GB 4793 (all parts);

---Replaced the ISO 14708 series with the informative GB 16174 (all parts);

---Replaced IEC 60601-1.2005/AMD1.2012 with GB 9706.1-2020;

---Replaced the source of the term "risk" in IEC 82304-1.2016 with IEC Guide63;

---Replaced the source of the term "cybersecurity" in IEC 82304-1.2016 with ISO /IEC /IEEE12207.2017 and added

note;

---Deleted Note 4 of 4.2;

--- Delete the last paragraph of A.1 in Appendix A about the description of different regulations applicable in international regulatory regions.

Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents.

Introduction

Health software refers to software that contributes to an individual's health using the observation and/or demonstration of measurable health parameters or clinical expertise.

This product is designed to run on a general-purpose computing platform and is intended to be marketed without specialized hardware for use by its manufacturer in managing

Manage, maintain or improve personal health or provide care. Some health software may cause dangerous situations, therefore, all health software is required to be inspected

Perform risk management. For health software that may lead to dangerous situations, risk controls are required to prevent harm or reduce the likelihood of harm occurring.

capability.

The line between health software and medical devices is difficult to distinguish. The developers of these software are usually not traditional medical device manufacturers.

The development process and safety requirements of these products should be limited "in advance" by appropriate standards.

Among various types of health software, health and wellness apps are a rapidly growing market, with hundreds of thousands of apps currently available.

programs, the most popular of which have millions of downloads each. Some of these applications are subject to medical device regulations, but most

Most are not bound by this. These apps are typically promoted directly to consumers through app stores without any formal evaluation. These applications

Often collecting sensitive personal information without appropriate privacy controls, providing advice on topics such as fertility, diet or activity, or

There is no evidence to support it. There are widespread concerns about the risks. At the

same time, health apps have proven effective in improving quality of life

quantity, and even extend lifespan, but it may not be adopted on a large scale. Many health organizations have assessment, accreditation and procurement requirements that meet local regulations

application project. These campaigns are ideal for any app looking to promote or sell their products to health and wellness service providers.

Manufacturers are important as providers want to ensure that the apps they recommend to patients are safe, reliable and effective. However, for

For application manufacturers wishing to offer products in multiple markets, standards and assessments differ for each country, organization or region.

The cost of the system is high.

In order to effectively evaluate the quality and reliability of health software, including health applications, the ISO 82304 series of standards and technologies have been developed successively

specifications, building on and integrating the guidelines and requirements for health software from many local and national health organizations around the world.

to ensure the software is safe, reliable and effective.

Currently, GB/T 42984 "Health Software" is divided into 2 parts.

---Part 1.General requirements for product safety. The purpose is to put forward requirements for the safety and network security of health software products and provide

Provides guidance on future regulation and identification of liabilities for health software products.

---Part 2.Health and Wellness Application Quality and Reliability. The purpose is to define the quality and usability of health applications.

Reliability-related questions and their supporting evidence to confirm (or determine) the quality and reliability of health applications.

The clauses marked with an asterisk (*) in this document have explanations and explanations related to the clause in Appendix A.

GB/T 43984.1-2023

health software

Part 1.General requirements for product safety

1.1 Purpose

This document specifies general requirements for health software product security.

This document applies to the security and cybersecurity of health software products, focusing primarily on requirements for manufacturers. Health software product design

It operates on a general computing platform and is expected to be available on the market without the need for specific hardware.

1.2 Application areas

This document covers the entire life cycle, including design, development, installation, validation, maintenance and processing of health software products.

In each referenced standard, the term "medical device" or "medical device software" is replaced, where appropriate, by the term "health software" or "health software product".

"product" instead.

If the term "patient" is used, whether in this document or in the referenced standard, it refers to a person whose health benefits from the use of health software

personnel.

This document does not apply to health software intended to be part of specific hardware designed for health use. Specifically, this document does not

Applies to.

a) Medical electrical equipment or systems covered by GB 9706 series;

b) In vitro diagnostic equipment covered by GB 4793 (all parts);

c) Implantable devices covered by GB 16174 (all parts).

NOTE. This document also applies to health software products (e.g. medical applications, health applications) intended for use with mobile computing platforms.

1.3 Compliance

Compliance with this document is determined by examining all documentation required by this document.

Conformity is assessed and documented by the manufacturer. Health software products may require external evaluation if they need to comply with regulatory requirements.

If this document normatively references sections or clauses of other standards with a safety or cybersecurity focus, the manufacturer may use the substitute

The alternative method demonstrates compliance with the requirements of this document. If the process results (including traceability) of these alternative methods are clearly