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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/Z 42217-2022

Medical device - Validation of software for medical device quality system

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

Table of Contents

foreword

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

drafting.

This document is modified to adopt ISO /T R80002-2.2017 "Medical Device Software Part 2.Quality System Software for Medical Devices"

Confirmation" was drafted, and the document type was adjusted from ISO technical report to my country's national standardization guiding technical document. This document is related to

The technical differences of ISO /T R80002-2.2017 and their reasons are as follows.

a) Regarding the normative reference documents, this document has been adjusted differently to adapt to the technical conditions of our country, and the adjustments are reflected in the

In Chapter 2 "Normative References", the specific adjustments are as follows.

* Added reference to GB/T 42061-2022;

* Added reference to GB/T 19000.

b) To facilitate the implementation of this document, "acronyms" (see 3.2) have been added.

The following editorial changes were made to this document.

--- In order to coordinate with existing regulations, the name of this document is changed to "Confirmation of Medical Device Quality System Software for Medical Devices";

--- In order to adapt to my country's national conditions, the company name and product name involved in Appendix C have been modified.

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

This document is intended to help the reader apply critical thinking, using a risk-based approach, to identify the processes used in a medical device quality system

Appropriate activities identified by the software.

The software applicable to this document involves the software used in the quality management system required by 4.1.6, 7.5.6 and 7.6 of GB/T 42061-2022.

software, software for production and service provision processes, and software for monitoring and measurement.

This document is a compilation of the experiences of those in the medical device industry who have engaged in such software validation and who have been responsible for creating auditable documentation. This document was developed

During the process, we always consider some problems and questions that we will encounter when conducting the software validation process of the medical device quality system, such as.

The content of the work that must be done, the amount of work necessary, and the manner in which the risk analysis is carried out. After an in-depth discussion it was concluded that in each case

In both cases, a set of activities (i.e., tools in the toolbox) are identified to provide some confidence in the software's ability to function as intended.

Due to factors such as the complexity of the software, the risk of harm involved, and the inherent attributes (e.g., quality, stability) of purchased software, activities are cleared.

Singles vary.

This document is intended to help stakeholders, including manufacturers, auditors and regulators, understand and apply GB/T 42061-

The requirements for software confirmation included in 4.1.6, 7.5.6 and 7.6 in 2022.

Medical Devices for Medical Device Quality

Confirmation of system software

1 Scope

This document applies to any medical device design, testing, component receipt, manufacturing, marking, packaging, distribution, and complaint handling.

Software, or automation software for any other aspect of the medical device quality system described in GB/T 42061.

This document applies to.

---Software for quality management system;

---Software for production and service provision;

--- Software for monitoring and measuring requirements.

Not suitable for.

--- software used as a component, part or accessory of a medical device, or

---Independent software for medical devices.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references

For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

this document.

GB/T 19000 Quality Management System Fundamentals and Terminology (GB/T 19000-2016, ISO 9000.2015, IDT)

GB/T 42061-2022 Medical Device Quality Management System Requirements for Regulations (ISO 13485.2016, IDT)

3.1 Terms and Definitions

The terms and definitions defined in GB/T 19000 and GB/T 42061 apply to this document.

3.2 Abbreviations

The following abbreviations apply to this document.

AVL. Approved Vendor List (ApprovedVendorList)

ID. Identification