NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 42061-2022

Medical devices - Quality management systems - Requirements for regulatory purposes

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for

Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This Document equivalently adopts ISO 13485.2016 Medical Devices - Quality Management

Systems - Requirements for Regulatory Purposes.

This Document made the minimum editorial modifications.

--- In order to coordinate with regulations, add NOTE 2 to "3.11 Medical Devices" in terms and definitions.

--- Add a row after 8.3.3 with "8.3.4 Rework" in the first column, and "8.7 Control of nonconforming outputs" in the second column correspondingly in the Table B.1; the original text is omitted.

Please note some contents of this Document may involve patents. The issuing agency of this

Document shall not assume the responsibility to identify these patents.

This Document was proposed by National Medical Products Administration.

This Document shall be under the jurisdiction of National Technical Committee on Quality Management and General Requirements for Medical Device of Standardization Administration

of China (SAC/TC 221).

Drafting organizations of this Document. Beijing Hua Guang Certification of Medical Devices

Co., Ltd.; National Institutes for Food and Drug Control; Shenzhen Mindray Bio-Medical Electronics Co., Ltd.; Neusoft Medical Systems Co., Ltd.; Beijing Wandong Medical Technology Co., Ltd.; Shanghai MicroPort Medical (Group) Co., Ltd.; Contec Medical Systems

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1 Scope

This Standard specifies requirements for a quality management system where an organization

needs to demonstrate its ability to provide medical devices and related services that consistently

meet customer and applicable regulatory requirements.

2 Normative References

The provisions in following documents become the essential provisions of this Document

through reference in this Document. For the dated documents, only the versions with the dates

indicated are applicable to this Document; for the undated documents, only the latest version

(including all the amendments) is applicable to this Document.

GB/T 19000-2016 Quality management systems - Fundamentals and vocabulary (ISO

9000.2015, IDT)

3 Terms and Definitions

For the purposes of this Document, the terms and definitions given in GB/T 19000-2016 and

the following apply.

4 Quality Management System

For each medical device type or medical device family, the organization shall establish and

maintain one or more files either containing or referencing documents generated to demonstrate

conformity to the requirement of this Standard and compliance with applicable regulatory

requirements.

The organization shall retain the records for at least the lifetime of the medical device as defined

by the organization, or as specified by applicable regulatory requirements, but not less than two