GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 03.100.70; 11.040.01

CCS C 30

GB/T 42061-2022 / ISO 13485:2016

Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

(ISO 13458:2016, IDT)

医疗器械 质量管理体系 用于法规的要求

Issued on: October 12, 2022 **Implemented on: November 01, 2023**

Issued by: State Administration for Market Regulation;

Standardization Administration of the People's Republic of China.

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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 Co., Ltd.; China National Institute of Standardization; Shandong Weigao Group Medical Polymer Co., Ltd.; and China National Medical Device Co., Ltd.

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Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

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. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g., technical support). This Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this Standard reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of this Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.

a) review and approve documents for adequacy prior to issue;

b) review, update as necessary and re-approve documents;

c) ensure that the current revision status of and changes to documents are identified;

d) ensure that relevant versions of applicable documents are available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;

g) prevent deterioration or loss of documents;

h) prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable regulatory requirements.

4.2.5 Control of records

Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

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 years from the medical device release by the organization.

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