SLOVENSKI STANDARD
oSIST prEN ISO 13485:2015

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Medicinski pripomočki - Sistemi vodenja kakovosti - Zahteve za zakonodajne namene (ISO/DIS 13485:2015)

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO/DIS 13485:2015)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO/DIS 13485:2015)

Dispositifs médicaux - Systèmes de management de la qualité - Exigences à des fins réglementaires (ISO/DIS 13485:2015)

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ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.040.01	Medicinska oprema na splošno	Medical equipment in general

oSIST prEN ISO 13485:2015 **en**

DRAFT INTERNATIONAL STANDARD

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Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

ICS: 11.040.01; 03.120.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

The committee responsible for this document is ISO/TC 210, Quality management and corresponding general aspects for medical devices.

This third edition cancels and replaces the second edition (ISO 13485:2003), which has been technically revised. Details of the changes between the second and this third edition of this Standard are described in Annex A.

This edition of ISO 13485 addresses quality assurance of product, customer requirements, and other elements of quality management systems for regulatory purposes.

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stage(s) of the life-cycle of a medical device including the design and development, production, storage and distribution, installation or servicing of medical devices, and the design, development, or provision of associated activities (e.g. technical support). The requirements in this standard may also be used by suppliers or other external parties providing product (e.g., sterilization services, calibration services, distribution services) to such organizations. Such a supplier or external party may voluntarily choose to conform to the requirements of this standard or may be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this standard expects that the organization:

- identifies its role(s) under applicable regulatory requirements,
- identifies the regulatory requirements that are applicable for its activities under these roles, and
- incorporates these applicable regulatory requirements within its quality management system.

This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for products that are necessary to meet customer and applicable regulatory requirements for safety and performance.

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by:

a) its organizational environment, changes in that environment, and the risks associated with that environment;
b) its varying needs;
c) its particular objectives;
d) the products it provides;
e) the processes it employs;
f) its size and organizational structure; and
g) applicable regulatory requirements.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

0.2 Process approach

This International Standard is based on a process approach to quality management.

Any activity that receives input(s) and converts them to output(s) can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it has to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach."

When used within a quality management system, such an approach emphasizes the importance of:

a) understanding and meeting requirements,
b) considering processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) improving processes based on objective measurement.

0.3 Relationship with ISO 9001

While this is a stand-alone standard, it is based on, and follows the format of, ISO 9001:2008 for the convenience of users in the medical device sector.

0.4 Compatibility with other management systems

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Medical devices – Quality management systems – Requirements for regulatory purposes

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle including the design and development, production, storage and distribution, installation, or servicing of a medical device and the design, development or provision of associated activities (e.g. technical support). The quality management system of the organization demonstrates the ability to consistently meet customer and applicable regulatory requirements. It may also be used by suppliers or external parties that provide goods and quality management system related services to such organizations.

The main objective of this International Standard is to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations providing medical devices. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001:2008 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001:2008 unless their quality management system conforms to all the requirements of ISO 9001:2008.

1.2 Application

All requirements of this International Standard are specific to organizations regardless of their type or size.

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 International Standard, which are applicable to the medical device(s), but which 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 arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls.

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

In this International standard the following terms or phases are used in the context described below:

- When a requirement is qualified by the phrase 'as appropriate', it is deemed to be 'appropriate' unless the organization can justify otherwise. A requirement is considered 'appropriate' if it is necessary for:
  - the product to meet requirements;
  - the organization to carry out corrective action; or
  - the organization to manage risks.
- When a requirement is required to be 'documented', it is also required to be established, implemented and maintained.
- When the term 'risk' is used, the application of the term is within the scope of this International standard and pertains to:
  - the safety or performance requirements or
  - meeting applicable regulatory requirements.
- When the term 'product' is used, it can also mean 'service'. Product applies to outputs that are intended for, or required by, a customer, or any intended output resulting from a product realization process.
- When the term 'regulatory requirements' is used, it encompasses statutory, regulatory and legal requirements. The application of the term 'regulatory requirements' is limited to requirements for the quality management system and the safety or performance of the medical device.
- Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, Quality management systems — Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 together with the following apply. The following definitions should be regarded as generic, as definitions provided in applicable regulatory requirements can differ slightly and take precedence.

3.1
advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise what action should be taken in the:

- use of a medical device,
- modification of a medical device,
- return of the medical device to the organization that supplied it, or
- destruction of a medical device

NOTE to entry: Issuance of an advisory notice might be required to comply with applicable regulatory requirements.

3.2
authorized representative
any natural or legal person who has received a documented mandate from a manufacturer to act on his behalf with respect to applicable regulatory requirements in (a) specified jurisdiction(s)

3.3
clinical evaluation
assessment and analysis of clinical evidence pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

3.4
complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or a service that affects the use of such medical devices

3.5
distributor
any natural or legal person in the supply chain who, on their own behalf, furthers the availability of a medical device to the end user. [SOURCE: GHTF/SG1/N055, definition 5.3]

Note 1 to entry: More than one distributor may be involved in the supply chain.

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

3.6
implantable medical device
medical device intended to:

- be totally or partially introduced into the human body or a natural orifice, or
- replace an epithelial surface or the surface of the eye, and

is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention

3.7
importer
any natural or legal person with responsibility to first make a medical device manufactured in one jurisdiction available in another specified jurisdiction

Note to entry: A distributor might also act as an importer where it is the first recipient of product from the manufacturer in a particular country.

3.8
labelling
written, printed, graphic or electronic information:

- affixed to a medical device or any of its containers or wrappers,
- accompanying a medical device, or
- provided for a medical device by other means

related to the identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

NOTE to entry: Applicable regulatory requirements refer to "labelling" as "information supplied by the manufacturer." This could include advertising, or marketing information.

3.9
life-cycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [SOURCE: ISO 14971:2007, definition 2.7]

3.10
manufacturer
any natural or legal person with responsibility for design or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether or not such a medical device is designed or manufactured by that person or on their behalf by another person(s)

Note 1 to entry: The definition of the "medical device manufacturer" differs from nation to nation and region to region. The organization needs to understand how the definition in the Standard will be interpreted in light of regulatory definitions for "medical device manufacturer" or equivalent term in the various nations and regions in which its medical devices are sold.

Note 2 to entry: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 3 to entry: The manufacturer's responsibilities are described in applicable regulatory requirements. These responsibilities might include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 4 to entry: 'Design or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of medical devices, and possibly other products, together for a medical purpose.

Note 5 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 6 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 7 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 8 to entry: To the extent that an accessory is subject to the applicable regulatory requirements of a medical device, the person responsible for the design or manufacture of that accessory is considered to be a manufacturer.

[Based on GHTF/SG1/N055:2009, definition 5.1].

3.11
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

