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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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## 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.

 