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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*



Reference number  
ISO 13485:2003(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 13485 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO 13485:1996), which has been technically revised. It also cancels and replaces ISO 13488:1996. Those organizations which have used ISO 13488 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

This edition of ISO 13485 has a revised title and addresses quality assurance of product, customer requirements, and other elements of quality system management.

## 0 Introduction

### 0.1 General

*This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services.*

*It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.*

Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

*It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.*

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. 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 inputs and converts them to outputs can be considered as a process.*

*For an organization to function effectively, it has to identify and manage numerous linked processes.*

Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

### 0.3 Relationship with other standards

#### 0.3.1 Relationship with ISO 9001

*While this is a stand-alone standard, it is based on ISO 9001.*

*Those clauses or subclauses that are quoted directly and unchanged from ISO 9001 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B.*

*Where the text of this International Standard is not identical to the text of ISO 9001, the sentence or indent containing that text as a whole is shown in italics (in blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex B.*

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