
**Quality systems — Medical devices —
Particular requirements for the application
of ISO 9001**

*Systèmes qualité — Dispositifs médicaux — Exigences particulières
relatives à l'application de l'ISO 9001*

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ISO 13485:1996

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Content

Page

1	Scope	1
2	Normative references	1
3	Definitions	1
4	Quality system requirements	3
4.1	Management responsibility.....	3
4.2	Quality system.....	3
4.3	Contract review	3
4.4	Design control	3
4.5	Document and data control	4
4.6	Purchasing	5
4.7	Control of customer-supplied product.....	5
4.8	Product identification and traceability.....	5
4.9	Process control	6
4.10	Inspection and testing	7
4.11	Control of inspection, measuring and test equipment.....	7
4.12	Inspection and test status	7
4.13	Control of nonconforming product.....	8
4.14	Corrective and preventive action.....	8
4.15	Handling, storage, packaging, preservation and delivery ..	9
4.16	Control of quality records	9
4.17	Internal quality audits	10
4.18	Training	10
4.19	Servicing.....	10
4.20	Statistical techniques.....	10

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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@isocs.iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

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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.

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.

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

[ISO 13485:1996](https://standards.iso.org/iso-13485-1996)

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Introduction

ISO 9001 is a general standard defining quality system requirements. ISO 13485 provides particular requirements for suppliers of medical devices that are more specific than the general requirements specified in ISO 9001.

In conjunction with ISO 9001, this International Standard defines requirements for quality systems relating to the design/development, production, installation and servicing of medical devices. It embraces all the principles of good manufacturing practice (GMP) widely used in the manufacture of medical devices. It can only be used in combination with ISO 9001 and is not an independent standard.

There are 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 described in clause 3.

Other International Standards specify more detailed particular requirements that are additional to those specified here. Suppliers should review the requirements and consider using the relevant International Standards in these areas.

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To assist in the understanding of the requirements of this International Standard, an international guidance standard is being prepared.

Quality systems — Medical devices — Particular requirements for the application of ISO 9001

1 Scope

This International Standard specifies, in conjunction with ISO 9001, the quality system requirements for the design/development, production and, when relevant, installation and servicing of medical devices.

This International Standard, in conjunction with ISO 9001, is applicable when there is a need to assess a medical device supplier's quality system.

As part of an assessment by a third party for the purpose of regulatory requirements, the supplier may be required to provide access to confidential data in order to demonstrate compliance with this International Standard. The supplier may be required to exhibit these data but is not obliged to provide copies for retention.

NOTE — In this International Standard the term "if appropriate" is used several times. When a requirement is qualified by this phrase, it is deemed to be "appropriate" unless the supplier can document a justification otherwise. A requirement is considered "appropriate" if its non-implementation could result in

- the product not meeting its specified requirements, and/or
- the supplier being unable to carry out corrective action.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.

ISO 11137:1995, *Sterilization of healthcare products — Requirements for validation and routine control — Radiation sterilization*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 apply, with the exception that the definition of "product" as given in ISO 9001 applies. In addition, the following definitions apply.

NOTE — These definitions should be regarded as generic, as definitions provided in national regulations may differ slightly.

3.1 medical device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTE — In addition to the medical device categories defined hereinafter, the term “medical device” also includes non-active medical devices and *in vitro* diagnostic devices.

3.2 active medical device: Any medical device (see 3.1) relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3.3 active implantable medical device: Any active medical device (see 3.1 and 3.2) which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

3.4 implantable medical device: Any medical device (see 3.1) intended

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

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

NOTE — This definition applies to implantable medical devices other than active implantable medical devices.

3.5 sterile medical device: Any medical device labelled as sterile. (See 3.6.1 of ISO 11137:1995.)

NOTE — Requirements for labelling a medical device as sterile may be subject to national or regional regulations or standards.

3.6 labelling: Written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device,

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

NOTE — For the purposes of this International Standard, the term “marking” as used in ISO 9001 is interpreted to mean “labelling”.

3.7 customer complaint: Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device (see 3.1) that has been placed on the market.

3.8 advisory notice: Notice issued by the supplier, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in

- the use of a medical device,

- the modification of a medical device,
- the return to the supplier of a medical device,
- the destruction of a medical device,

for the purpose of corrective or preventive action and in compliance with national and regional regulatory requirements.

4 Quality system requirements

4.1 Management responsibility

The requirements given in 4.1 of ISO 9001:1994 apply.

4.2 Quality system

4.2.1 General

The requirements given in 4.2.1 of ISO 9001:1994 apply.

Particular requirement for all medical devices:

The supplier shall establish and document the specified requirements.

NOTE — If this International Standard is used for compliance with regulatory requirements, the relevant requirements of the regulations should be included in the specified requirements.

4.2.2 Quality system procedures

The requirements given in 4.2.2 of ISO 9001:1994 apply.

4.2.3 Quality planning

The requirements given in 4.2.3 of ISO 9001:1994 apply.

Particular requirement for all medical devices:

The supplier shall establish and maintain a file containing documents defining product specifications and quality system requirements (process and quality assurance) for

- complete manufacturing, and
- installation and servicing, if appropriate,

for each type/model of medical device, or referring to the location(s) of this information (see 4.5.2 and 4.16).

4.3 Contract review

The requirements given in 4.3 of ISO 9001:1994 apply.

4.4 Design control

4.4.1 General

The requirements given in 4.4.1 of ISO 9001:1994 apply.

Particular requirement for all medical devices:

Throughout the design process, the supplier shall evaluate the need for risk analysis and maintain records of any risk analyses performed.

4.4.2 Design and development planning

The requirements given in 4.4.2 of ISO 9001:1994 apply.

4.4.3 Organizational and technical interfaces

The requirements given in 4.4.3 of ISO 9001:1994 apply.

4.4.4 Design input

The requirements given in 4.4.4 of ISO 9001:1994 apply.

4.4.5 Design output

The requirements given in 4.4.5 of ISO 9001:1994 apply.

4.4.6 Design review

The requirements given in 4.4.6 of ISO 9001:1994 apply.

4.4.7 Design verification

The requirements given in 4.4.7 of ISO 9001:1994 apply.

4.4.8 Design validation

The requirements given in 4.4.8 of ISO 9001:1994 apply.

Particular requirement for all medical devices:

As part of design validation, the supplier shall perform and maintain records of clinical evaluations.

NOTE — Clinical evaluation may include a compilation of relevant scientific literature, historical evidence that similar designs and/or materials are clinically safe, or a clinical investigation or trial, to ensure that the device performs as intended. National or regional regulations may require actual clinical investigations or trials.

4.4.9 Design changes

The requirements given in 4.4.9 of ISO 9001:1994 apply.

4.5 Document and data control**4.5.1 General**

The requirements given in 4.5.1 of ISO 9001:1994 apply.

4.5.2 Document and data approval and issue

The requirements given in 4.5.2 of ISO 9001:1994 apply.

Particular requirement for all medical devices:

The supplier shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that specifications to which medical devices have been manufactured are available for at least the lifetime of the medical device as defined by the supplier.

4.5.3 Document and data changes

The requirements given in 4.5.3 of ISO 9001:1994 apply.

4.6 Purchasing**4.6.1 General**

The requirements given in 4.6.1 of ISO 9001:1994 apply.

4.6.2 Evaluation of subcontractors

The requirements given in 4.6.2 of ISO 9001:1994 apply.

4.6.3 Purchasing data

The requirements given in 4.6.3 of ISO 9001:1994 apply.

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Particular requirement for all medical devices:

To the extent required by the particular requirements for traceability given in 4.8, the supplier shall retain copies (see 4.16) of relevant purchasing documents. [ISO 13485:1996](https://standards.iteh.ai/catalog/standards/sist/b0aa9d3d-2a06-496c-bbdd-b358ff2cde3d/iso-13485-1996)

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4.6.4 Verification of purchased product

The requirements given in 4.6.4 of ISO 9001:1994 apply.

4.7 Control of customer-supplied product

The requirements given in 4.7 of ISO 9001:1994 apply.

4.8 Product identification and traceability

The requirements given in 4.8 of ISO 9001:1994 apply.

Particular requirements for all medical devices:**a) Identification**

The supplier shall establish and maintain procedures to ensure that medical devices returned to the supplier for reprocessing to specified requirements are identified and distinguished at all times from normal production (see 4.15.1).

b) Traceability

The supplier shall establish, document and maintain procedures for traceability. The procedures shall define the extent of traceability and shall facilitate corrective and preventive action (see 4.14).