Dansk standard

DS/EN ISO 13485

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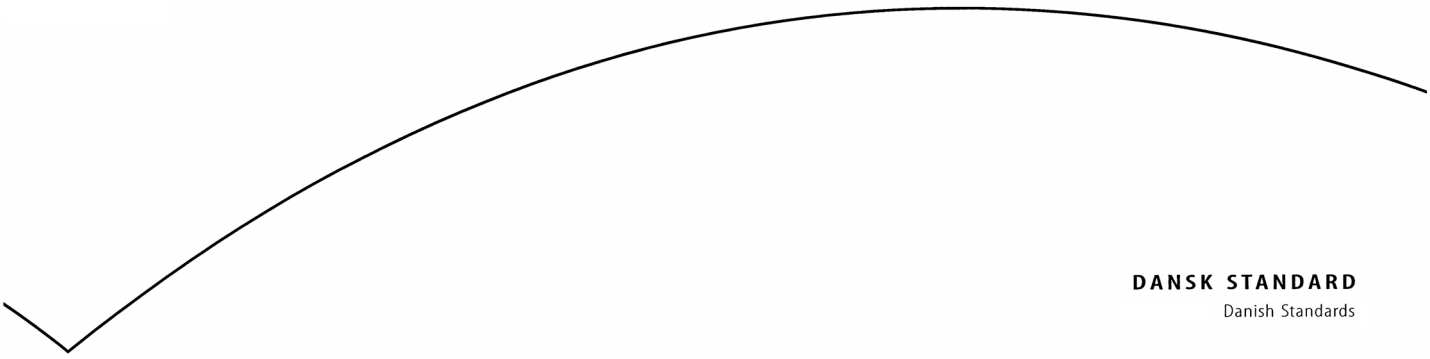
Medicinsk udstyr – Kvalitetsledelses-systemer – Krav til lovmæssige formål

Medical devices – Quality management systems – Requirements for regulatory purposes



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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485

February 2012

ICS 03.120.10; 11.040.01

Supersedes EN ISO 13485:2003

English version

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

Dispositifs médicaux - Systèmes de manegement de la qualité - Exigences à des fins réglementaires (ISO 13485:2003)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2003)

This European Standard was approved by CEN on 24 January 2012.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Foreword

The text of the International Standard ISO 13485:2003 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices, Working Group 1". The transposition into a European Standard has been managed by the CEN-CENELEC Management Centre (CCMC) with the assistance of the CEN-CENELEC Technical Committee 3 "Quality Management and corresponding general aspects for medical devices".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2012, and conflicting national standards shall be withdrawn at the latest by August 2012.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports quality system requirements of EU Medical Devices Directives. Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of the quality systems of the Medical Devices Directives. It is important that the organization and the Notified Body identify the regulatory requirements that are not covered by the standard. The Annexes Z of this standard shall be used for this purpose, describing the relationship between this European Standard and the conformity assessment requirements of the Medical Devices Directives.

This document supersedes EN ISO 13485:2003.

NOTE The following is specifically intended for organizations that need to comply with one or more of the European Directives for medical devices (90/385/EEC, 93/42/EEC and 98/79/EC) in order to affix CE marking on their products and for other parties involved in that process whilst other Directives might also require a CE marking.

Where organizations wish to implement quality systems [1)] in conformance with Directives 90/385/EEC, 93/42/EEC and 98/79/EC, they may use EN ISO 13485:2012. EN ISO 13485:2012 provides a framework to enable a manufacturer to meet some of the quality system requirements for an EC Declaration of Conformity (Annex 2 and Annex 5 of Directive 90/385/EEC; Annex II, V and VI of Directive 93/42/EEC; or Annex III, IV and VII of Directive 98/79/EC).

In seeking compliance with the quality systems requirements of the Medical Devices Directives, organizations may exclude specific requirements from EN ISO 13485. The table below shows the exclusions that are permitted.

1) The European Directives use the term "quality system" whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Directive 90/385/EEC	Directive 93/42/EEC	Directive 98/79/EC
For Annex 2, no exclusions are permitted	For Annex II, no exclusions are permitted	For Annex III and IV, no exclusions are permitted
For Annex 5, exclusion of 7.3 of EN ISO 13485 is permitted	For Annex V, exclusion of 7.3 from EN ISO 13485 is permitted	For Annex VII, exclusion of 7.3 from EN ISO 13485 is permitted
	For Annex VI, exclusion of 7.3, 7.5.1 and 7.5.2 from EN ISO 13485 are permitted	

It should be noted that where the exclusions described in 1.2 of EN ISO 13485:2012 are exceeded, conformity to EN ISO 13485:2012 shall not be claimed.

The requirements in ISO 13485:2003 describe a systematic approach, within which manufacturers can identify, review and decide on the appropriate manner to incorporate regulatory requirements, other standards, and regulatory guidance documents into their quality management system. In this context, EN ISO 13485 requires the manufacturer to provide quality management system elements including: necessary resources, infrastructure and competent personnel; documentation and records for the operation of the quality management system; systems of internal audit and management review; systems to address nonconformity, corrective action and preventive action.

It should be noted that EN ISO 13485:2012 is a quality management system for medical devices specifically for regulatory purposes. It is based on EN ISO 9001:2000 but in particular the requirements for “customer satisfaction” and “continual improvement” have been modified. Therefore, while EN ISO 13485:2012 has the same format as EN ISO 9001:2000 and most of the same requirements, compliance with EN ISO 13485:2012 does not provide conformity with EN ISO 9001:2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13485:2003 has been approved by CEN as a EN ISO 13485:2012 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 90/385/EEC

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ZA.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 90/385/EEC on active implantable medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:2012), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZA.1 and ZA.2 confers presumption of conformity with the requirements on a manufacturer's quality system[2)] as given in Annexes 2 and 5 of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZA explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes 2 and 5 of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZA.1 and ZA.2 if an application to a Notified Body:

- contains the necessary quality system documentation;
- has been reviewed and approved by a Notified Body,

and the undertakings listed in the application are correctly executed by the manufacturer.

ZA.2 Relationship with Annex 2 of Directive 90/385/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex 2, as outlined in Table ZA.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex 2 of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

2) This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZA.1 — Relationship between Annex 2 of Directive 90/385/EEC and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 2	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1st indent		Not covered
3.1 second sentence 2nd indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex 2 unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second sentence 3rd indent		Not covered
3.1 second sentence 4th indent		Not covered
3.1 second sentence 5th indent		Not covered
3.2 first paragraph		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 90/385/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 second paragraph, first sentence	4.1, 4.2	Covered
3.2 second paragraph, second sentence	4.1, 4.2	Covered
3.2 second paragraph, third sentence		Not covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2, 5.1.1	Covered
3.2 third paragraph (b) 1st indent	4.2.2, 5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3rd indent	4.1, 7.4, 8.5.1	Covered provided that the processes are documented in accordance with 4.2.1.
3.2 third paragraph (c) 1st indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled and there is a description of the standards that will be

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		applied.
3.2 third paragraph (c) 2nd indent	7.3.1, 7.3.5, 7.3.6, 7.3.7	Covered
3.2 third paragraph (c) 3rd indent		Not covered
3.2 third paragraph (c) 4th indent		Not covered
3.2 third paragraph (c) 5th indent		Not covered
3.2 third paragraph (d) 1st indent, sterilization	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (d) 1st indent, purchasing	7.4	Covered
3.2 third paragraph (d) 1st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (d) 2nd indent	4.2, 7.5.3,	Covered
3.2 third paragraph (e)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

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ZA.3 Relationship with Annex 5 of Directive 90/385/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex 5, as outlined in Table ZA.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex 5 of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the directive.

Table ZA.2 — Relationship between Annex 5 of Directive 90/385/EEC and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 5	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1first paragraph		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 2nd indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex 5 unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 3rd indent		Not covered
3.1 second paragraph 4th indent		Not covered
3.1 second paragraph 5th indent		Not covered
3.1 second paragraph 6th indent		Not covered
3.2 first paragraph		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 90/385/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b) 1st indent	5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3rd indent	4.1, 7.4, 8.5.1	Covered provided that the processes are documented in accordance with 4.2.1.
3.2 third paragraph (c)	6.4, 7.5.1, 7.5.2	Covered

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1st indent, sterilization		
3.2 third paragraph (c) 1st indent, purchasing	7.4	Covered
3.2 third paragraph (c) 1st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (c) 2nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 90/385/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

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Annex ZB
(informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 93/42/EEC

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ZB.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 93/42/EEC on medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:2012), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZB.1, ZB.2 and ZB.3 confers presumption of conformity with the requirements on a manufacturer's quality system[3)] as given in Annexes II, V and VI of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZB explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes II, V and VI of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZB.1, ZB.2 and ZB.3 if the application to a Notified Body:

- contains the necessary quality system documentation;
- has been reviewed and approved by a Notified Body,

and the undertakings listed in the application are correctly executed by the manufacturer.

ZB.2 Relationship with Annex II of Directive 93/42/EEC

Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of Annex II, as outlined in Table ZB.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex II of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

3) This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

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Table ZB.1 — Relationship between Annex II of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1st indent		Not covered
3.1 second sentence 2nd indent		Not covered
3.1 second sentence 3rd indent		Not covered
3.1 second sentence 4th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second sentence 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 7th indent		Not covered
3.2 first paragraph first sentence		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 first paragraph second sentence	4.1, 4.2	Covered
3.2 second paragraph		Not covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2, 5.1.1	Covered
3.2 third paragraph (b) 1st indent	4.2.2, 5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3rd indent	4.1, 4.2, 7.4, 8.5.1	Covered provided that control processes are documented in accordance with 4.2.1.
3.2 third paragraph (c)	7.1, 7.2, 7.3	Covered
3.2 third paragraph (c) 1st indent		Not covered
3.2 third paragraph (c) 2nd	7.1, 7.2, 7.3.2, 7.3.3,	Covered provided that there is a description of

indent	7.3.6	the standards that will be applied.
3.2 third paragraph (c) 3rd indent	7.3.1, 7.3.5, 7.3.6, 7.3.7	Covered
3.2 third paragraph (c) 4th indent	7.3.2, 7.3.3, 7.3.5, 7.3.6	Covered
3.2 third paragraph (c) 5th indent		Not covered
3.2 third paragraph (c) 6th indent		Not covered
3.2 third paragraph (c) 7th indent		Not covered
3.2 third paragraph (c) 8th indent		Not covered
3.2 third paragraph (c) 9th indent		Not covered
3.2 third paragraph (c) 10th indent		Not covered
3.2 third paragraph (d) 1st indent, sterilization	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (d) 1st indent, purchasing	7.4	Covered
3.2 third paragraph (d) 1st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (d) 2nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (e)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

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ZB.3 Relationship with Annex V of Directive 93/42/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex V, as outlined in Table ZB.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex V of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZB.2 — Relationship between Annex V of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex V	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 2nd indent		Not covered
3.1 second paragraph 3rd indent		Not covered
3.1 second paragraph 4th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex V unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 7th indent		Not covered
3.1 second paragraph 8th indent 3.1 second paragraph 8th indent (i) 3.1 second paragraph 8th indent (ii)		Not covered
3.2 first paragraph		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC.

		The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2	Covered
3.2 third paragraph (b) 1st indent	5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.5.2	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the directive are fulfilled.
3.2 third paragraph (b) 3rd indent	4.1, 4.2.1, 7.4, 8.5.1	Covered provided that control processes are documented in accordance with 4.2.1.
3.2 third paragraph (c) 1st indent, sterilization	6.4, 7.5.1, 7.5.2	Covered provided that the explicit requirements of the Directive are incorporated into the quality system documentation.
3.2 third paragraph (c) 1st indent, purchasing	7.4	Covered
3.2 third paragraph (c) 1st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (c) 2nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

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ZB.4 Relationship with Annex VI of Directive 93/42/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex VI, as outlined in Table ZB.3. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex VI of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZB.3 — Relationship between Annex VI of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex VI	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1first paragraph		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 2nd indent		Not covered
3.1 second paragraph 3rd indent		Not covered
3.1 second paragraph 4th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex VI unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5th indent	4.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6th indent	4.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 7th indent		Not covered
3.1 second paragraph 8th indent 3.1 second paragraph 8th indent (i) 3.1 second paragraph 8th indent (ii)		Not covered

3.2 first sentence		Not covered
3.2 second and third sentences	4.1, 4.2	Covered
3.2 second paragraph 1st indent	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 second paragraph 2nd indent	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.
3.2 second paragraph 3rd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 second paragraph 4th indent	4.1, 4.2, 6.1	Covered
3.2 second paragraph 5th indent	4.1, 4.2.1, 7.4, 8.5.1	Covered provided that control processes are documented in accordance with 4.2.1.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 93/42/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

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Annex ZC
(informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 98/79/EC

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ZC.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:2012), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZC.1, ZC.2 and ZC.3 confers presumption of conformity with requirements on a manufacturer's quality system[4)] as given in Annexes III, IV and VII of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZC explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes III, IV and VII of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZC.1, ZC.2 and ZC.3 if the application to a Notified Body:

- contains the necessary quality system documentation;
- has been reviewed and approved by a Notified Body,

and the undertakings listed in the application are correctly executed by the manufacturer.

ZC.2 Relationship with Annex III of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of Annex III, as outlined in Table ZC.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex III of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

4) This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZC.1 — Relationship between Annex III of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex III	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3 first sentence		Not covered
3 1st indent		Not covered
3 2nd indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in Annex III unless the explicit legal requirements are incorporated into the quality system documentation.
3 3rd indent	4.2, 7.1, 7.3, 7.5	Covered
3 4th indent		Not covered
3 5th indent		Not covered
3 6th indent		Not covered
3 7th indent	6.4, 7.5.1.2, 7.5.1.3, 7.5.2	Covered
3 8th indent	4.2.1, 7.1.8.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.3, 8.2.4	Covered
3 9th indent		Not covered
3 10th indent	4.2.4, 8.2.4	Covered
3 11th indent		Not covered
3 12th indent		Not covered
3 13th indent		Not covered

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ZC.3 Relationship with Annex IV of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex IV, as outlined in Table ZC.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex IV of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZC.2 — Relationship between Annex IV of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex IV	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1first paragraph		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 2nd indent		Not covered
3.1 second paragraph 3rd indent		Not covered
3.1 second paragraph 4th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex IV unless the explicit legal requirements of the Directive are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5th indent		Not covered
3.1 second paragraph 6th indent		Not covered
3.1 second paragraph 7th indent		Not covered
3.2 first sentence		Not covered
3.2 second sentence	4.1, 4.2	Covered
3.2 second paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 second paragraph (b)	4.2.2	Covered
3.2 second paragraph (b) 1st indent	5.5.1, 5.5.2	Covered
3.2 second paragraph (b) 2nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 second paragraph (c) 1st indent		Not covered

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3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 3rd indent	4.2, 7.1, 7.3, 7.5	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 4th indent		Not covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 5th indent		Not covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 6th indent		Not covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 7th indent	6.4, 7.5.1.2, 7.5.1.3, 7.5.2	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 8th indent	4.2.1, 7.1.8.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.3, 8.2.4	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 9th indent		Not covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 10th indent	4.2.4, 8.2.4	Covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 11th indent		Not covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 12th indent		Not covered
3.2 second paragraph (c) 2nd indent reference to Annex III – section 3 13th indent		Not covered
3.2 second paragraph (d) 1st indent	6.4, 7.5.1, 7.5.2	Covered

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3.2 second paragraph (d) 2nd indent	7.4	Covered
3.2 second paragraph (d) 3rd indent	7.5.1, 7.5.2, 7.4, 4.2	Covered
3.2 second paragraph (e)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

ZC.4 Relationship with Annex VII of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex VII, as outlined in Table ZC.3. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex VII of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZC.3 — Relationship between Annex VII of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 1st indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex VII unless the explicit legal requirements of the Directive are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 1st indent		Not covered
3.1 second paragraph 1st indent		Not covered
3.2 first paragraph		Not covered
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2	Covered

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3.2 third paragraph (b) 1st indent	5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 third paragraph (c) 1st indent	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (c) 2nd indent	7.4	Covered
3.2 third paragraph (c) 3rd indent	4.2, 7.5.1, 7.5.2, 7.4	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 98/79/EC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

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INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

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.

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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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0.3.2 Relationship with ISO/TR 14969

ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.

0.4 Compatibility with other management systems

This International Standard follows the format of ISO 9001 for the convenience of users in the medical device community.

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.

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Medical devices — Quality management systems — Requirements for regulatory purposes

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1 Scope

1.1 General

This International 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 requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 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 unless their quality management systems conform to all the requirements of ISO 9001 (see Annex B).

1.2 Application

All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations 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 [see 4.2.2 a) and 7.3].

If any requirement(s) in Clause 7 of this International Standard is(are) not applicable due to 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 [see 4.2.2 a)].

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 [see 4.1 a)].

In this International Standard the terms "if appropriate" and "where appropriate" are used several times. When a requirement is qualified by either of these phrases, it is deemed to be "appropriate" unless the organization can document a justification otherwise. A requirement is considered "appropriate" if it is necessary in order for

- *the product to meet specified requirements, and/or*
- *the organization to carry out corrective action.*

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2 Normative references

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

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this *document*, the terms and definitions given in ISO 9000 apply, *together with the following.*

The following terms, used in this edition of *ISO 13485* to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier ----------> organization ----------> customer

The term "organization" replaces the term "supplier" used in ISO 13485:1996, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

Wherever requirements are specified as applying to "medical devices", the requirements apply equally to related services as supplied by the organization.

The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.

3.1
active implantable medical device
active medical device 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

3.2
active medical device
medical device 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
advisory notice
notice issued by the organization, 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 of the medical device to the organization that supplied it, or*

— *the destruction of a medical device*

NOTE Issue of an advisory notice might be required to comply with national or regional regulations.

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