Meditsiiniseadmed. Kvaliteedijuhtimissüsteem. Normatiivsed nõuded

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

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See Eesti standard EVS-EN ISO 13485:2012 sisaldab Euroopa standardi EN ISO 13485:2012+AC:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13485:2012 consists of the English text of the European standard EN ISO 13485:2012+AC:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.02.2012.	Date of Availability of the European standard is 15.02.2012.
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ICS 03.120.10, 11.040.01

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485

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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)

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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of an identical text or by endorsement, at the latest by August 2012, and conflicting national standards shall be withdrawn at the latest by August 2012.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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