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Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

EESTI STANDARDIKESKUS
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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 13485:2016 sisaldab Euroopa standardi EN ISO 13485:2016 ja selle paranduste AC:2016 ja AC:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13485:2016 consists of the English text of the European standard EN ISO 13485:2016, its corrigendum AC:2016 and AC:2018.
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 02.03.2016, parandus AC 21.12.2016.	Date of Availability of the European standard is 02.03.2016, for corrigendum AC 21.12.2016.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 03.120.10, 11.040.01

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485

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ICS 03.100.70; 11.040.01

Supersedes CEN ISO/TR 14969:2005, EN ISO 13485:2012

English version

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Dispositifs médicaux - Systèmes de management de la qualité - Exigences à des fins réglementaires (ISO 13485:2016)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016)

This European Standard was approved by CEN on 30 January 2016.

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.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

This document consolidates EN ISO 13485:2016 and the corrigendum EN ISO 13485:2016/AC:2018.

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European foreword

This document (EN ISO 13485:2016) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

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 September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

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.

▌〈AC〉 This document supersedes EN ISO 13485:2012 and CEN ISO/TR 14969:2005 〈AC〉▐.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directives, see informative Annex ZA, ZB and ZC, which are integral parts of this document.

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, Former Yugoslav Republic of Macedonia, 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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, ZB and ZC, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

This document includes the corrigendum EN ISO 13485:2016/AC:2018 which corrects the European foreword, Annex ZA, Annex ZB and Annex ZC.

Table 1 — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 9000:2015	EN ISO 9000:2015	ISO 9000:2015

Endorsement notice

The text of ISO 13485:2016 has been approved by CEN as EN ISO 13485:2016 without any modification.

Annex ZA
(informative)

[AC] Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 90/385/EEC (as amended) [AC]

ZA.0 General

[AC] This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Union 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 (as amended) on active implantable medical devices. [AC]

Once this European Standard is cited in the Official Journal of the European Union under Directive 90/385/EEC (as amended) and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this European Standard given in Table ZA.1 or Table ZA.2 confer, within the limits of the scope of this European Standard, a presumption of conformity with the requirements on a manufacturer's quality system as given in Annexes 2 and 5 of that Directive and associated EFTA regulations. This Annex ZA explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

[AC] *deleted text* [AC]

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 this European Standard and therefore not covered by this European 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.

NOTE 1 Where a reference from a clause of this European Standard to the risk management process is made, the risk management process needs to be in compliance with [AC] Directive 90/385/EEC [AC], as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 4, 5, 8, 9 and 10 of the Directive. [AC] *deleted text* [AC]

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When a requirement does not appear in Table ZA.1 or ZA.2, it means that it is not addressed by this European Standard.

NOTE 5 This annex uses the term "quality system" as used in the Directive whereas this European Standard uses the term "quality management system" in accordance with ISO terminology.

ZA.1 Relationship with Annex 2 of Directive 90/385/EEC (as amended)

Compliance with this European Standard 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.

Table ZA.1 — Correspondence between this European Standard and Annex 2 of Directive 90/385/EEC (as amended)

Paragraph of Directive 90/385/EEC, Annex 2	Clause(s) of this European Standard	Comments/Qualifying remarks
3.1, 1st sentence		Not covered.
3.1, 2nd sentence, 1st indent		Not covered.
3.1, 2nd sentence, 2nd indent	4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5	Covered. The documentation required in this European Standard covers the quality system documentation meant in 3.2 of Annex 2 when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1, 2nd sentence, 3rd indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered in part. This European Standard requires top management commitment to implementation of the quality system and that documented procedures are implemented but does not require a signed undertaking.
3.1, 2nd sentence, 4th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered in part. This European Standard requires maintenance of the approved quality system but does not require a signed undertaking.
3.1, 2nd sentence, 5th indent		Not covered. This European Standard includes requirements on post-market surveillance, and reporting adverse events and field safety corrective actions to authorities but does not cover all the details required by the Directive including timescales for reporting.
3.2, 1st paragraph		Not covered. The application of this European Standard does not by itself ensure the fulfilment of all regulatory requirements of the Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2, 2nd paragraph, 1st sentence	4.1, 4.2	Covered.
3.2, 2nd paragraph, 2nd sentence	4.1, 4.2	Covered.
3.2, 2nd paragraph, 3rd sentence	4.1, 4.2, 7	Covered provided quality management system documentation makes possible a uniform interpretation of the quality policies and procedures, such as quality programs, quality plans, quality manuals and quality records, and that the applicable documentation listed in 3.2 of Annex 2 is incorporated into the quality system documentation.

Paragraph of Directive 90/385/EEC, Annex 2	Clause(s) of this European Standard	Comments/Qualifying remarks
3.2, 3rd paragraph (a)	4.2.1, 4.2.3, 5.1, 5.3, 5.4.1	Covered.
3.2, 3rd paragraph (b)	4.2.2, [AC> 5.1 <AC]	Covered.
3.2, 3rd paragraph (b), 1st indent	4.2.2, 5.1, 5.5.1, 5.5.2	Covered.
3.2, 3rd paragraph (b), 2nd indent	4.1, 5.6, 7.1, 8.2.4, 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 3rd paragraph (b) 3rd indent	1, 4.1, 4.2, 7.4, [AC> 8.2.2 <AC]	Covered.
3.2 3rd paragraph (c) 1st indent	4.2, 7.3.2, 7.3.3, 7.3.7, 7.3.9, 7.3.10	Covered provided that the applicable quality management system documentation includes design specifications identifying standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply when harmonized standards are not applied in full.
3.2, 3rd paragraph (c), 2nd indent	7.3.1, 7.3.6, 7.3.7, 7.3.9	Covered.
3.2, 3rd paragraph (c), 3rd indent		Not covered.
3.2, 3rd paragraph (c), 4th indent	7.3.6, 7.3.7	Covered provided that the quality management system records include the pre-clinical evaluation.
3.2, 3rd paragraph (c), 5th indent		Not covered. Clause 7.3.7 does not include the details of Annex 7.
3.2, 3rd paragraph (d), 1st indent	4.2, 6.4, 7.1, 7.4 7.5	Covered provided that the quality management system documentation includes relevant documents and records in regards to sterilization and purchasing.
3.2, 3rd paragraph (d), 2nd indent	4.2, 7.5.8, 7.5.9	Covered.
3.2, 3rd paragraph (e)	4.2, 7.1, 7.4.3, [AC> *deleted text* <AC], 7.5.9.1, 7.6, 8.2.6	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.
6.1		Not covered. The specific time periods in Directive are not specified in 4.2.4 or 4.2.5.

ZA.2 Relationship with Annex 5 of Directive 90/385/EEC (as amended)

Compliance with this European Standard 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 — Correspondence between this European Standard and Annex 5 of Directive 90/385/EEC (as amended)

Paragraph of Directive 90/385/EEC, Annex 5	Clause(s) of this European Standard	Comments/Qualifying remarks
3.1, 1st paragraph		Not covered.
3.1, 2nd paragraph, 1st indent		Not covered.
3.1, 2nd paragraph, 2nd indent	4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5	Covered. The documentation required in this European Standard covers the quality system documentation meant in 3.2 of Annex 5 when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1, 2nd paragraph, 3rd indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd paragraph, 4th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd paragraph, 5th indent	4.1, 4.2	Covered in part provided that quality management system includes the technical documentation relating to the applicable approved type(s) of medical device(s). Reference to the EC type-examination certificate is not covered.
3.1, 2nd paragraph, 6th indent		Not covered. This European Standard includes requirements on post market surveillance, and reporting adverse events and field safety corrective actions to authorities but does not cover all the details required by the Directive including timescales for reporting
3.2, 1st paragraph		Not covered. Reference to the EC type-examination certificate is not covered.
3.2, 2nd paragraph	4.1, 4.2	Covered.
3.2, 3rd paragraph (a)	4.2.1, 4.2.3, 5.1, 5.3, 5.4.1	Covered.
3.2, 3rd paragraph (b), 1st indent	5.5.1, 5.5.2	Covered.
3.2, 3rd paragraph (b), 2nd indent	4.1, 5.6, 7.1, 8.2.4, 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, 3rd paragraph (b), 3rd indent	1, 4.1, 4.2, 7.4, [AC> 8.2.2 <AC]	Covered.
3.2, 3rd paragraph (c), 1st indent	4.2, 6.4, 7.1, 7.4, 7.5	Covered provided that the quality management system documentation includes relevant documents and records in regards to sterilization and purchasing.
3.2, 3rd paragraph (c), 2nd indent	4.2, [AC> 7.5.8, 7.5.9 <AC]	Covered.
3.2, 3rd paragraph (d)	7.1, 7.4.3, 7.6, 8.2.6	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation.

[AC] 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. [AC]

Annex ZB
(informative)

[AC> Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 93/42/EEC (as amended) <AC]

ZB.0 General

[AC> This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Union 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 (as amended) on medical devices. <AC]

Once this European Standard is cited in the Official Journal of the European Union under Directive 93/42/EEC (as amended) and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this European Standard given in Tables ZB.1, ZB.2 and ZB.3 confer, within the limits of the scope of this European Standard, a presumption of conformity with the requirements on a manufacturer's quality system as given in Annexes II, V and VI of that Directive and associated EFTA regulations. This Annex ZB explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

[AC> *deleted text* <AC]

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 this European Standard and therefore not covered by this European 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 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.

NOTE 1 Where a reference from a clause of this European Standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive. [AC> *deleted text* <AC]

NOTE 3 This Annex ZB is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When a requirement does not appear in Table ZB.1, ZB.2 or ZB.3, it means that it is not addressed by this European Standard.

NOTE 5 This annex uses the term "quality system" as used in the Directive whereas this European Standard uses the term "quality management system" in accordance with ISO terminology.

ZB.1 Relationship with Annex II of Directive 93/42/EEC (as amended)

Compliance with this European Standard 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.

Table ZB.1 — Correspondence between this European Standard and Annex II of Directive 93/42/EEC (as amended)

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of this European Standard	Comments/Qualifying remarks
3.1, 1st sentence		Not covered.
3.1, 2nd sentence, 1st indent		Not covered.
3.1, 2nd sentence, 2nd indent		Not covered.
3.1, 2nd sentence, 3rd indent		Not covered.
3.1, 2nd sentence, 4th indent	4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5	Covered. The documentation required in this European Standard covers the quality system documentation meant in 3.2 of Annex II when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1, 2nd sentence, 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd sentence, 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd sentence, 7th indent 3.1, 7th indent (i) 3.1, 7th indent (ii)		Not covered. This European Standard includes requirements on post market surveillance, and reporting adverse events and field safety corrective actions to authorities but does not cover all the details required by the Directive including timescales for reporting.
3.2, 1st paragraph, 1st sentence		Not covered. The application of this European Standard does not by itself ensure the fulfilment of all regulatory requirements of the Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted become part of the quality system in the meaning of the Directive.
3.2, 1st paragraph, 2nd sentence	4.1, 4.2, 7.1	Covered.
3.2, 2nd paragraph	4.1, 4.2, 7	Covered provided quality management system documentation makes possible a uniform interpretation of the quality policies and procedures, such as quality programs, quality plans, quality manuals and quality records, and that the applicable documentation listed in 3.2 of Annex II is incorporated into the quality system documentation.
3.2, 3rd paragraph (a)	4.2.3, 5.1, 5.3, 5.4.1	Covered.