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Medicinsk udstyr – Kvalitetsledelses-systemer – Krav angående opfyldelse af lovmæssige formål

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

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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 13485:2012

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.

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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.

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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of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.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.

This document supersedes EN ISO 13485:2012.

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.

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)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC (as amended)

ZA.0 General

This European standard has been prepared under a Commission's standardisation request M/023 to provide one voluntary means of conforming to requirements of Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [OJ L 189].

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.

EN ISO 13485:2016 provides requirements for a quality system applicable to medical devices. Because this standard describes a quality system that is connected in part or in whole to the conformity assessment requirements of 90/385/EEC (as amended), it is not meaningful to link individual clauses of the standard to specific Essential Requirements. Compliance with all the normative clauses in EN ISO 13485 will ensure that a process is in place to address quality system aspects related to medical devices, which are included in the conformity assessment annexes of the Directive. However, because this is an adoption of an international standard, intended to be applicable in jurisdictions all over the world, it is not the primary goal of the standard to cover exactly the European quality system requirements. Therefore, for all of the quality system requirements, conformity is not entirely achieved by complying only with the requirements specified in this standard. Manufacturers and conformity assessment bodies will need to feed the quality system requirements in the applicable Annex of the Directive into the processes provided by the standard. Explanation on the correspondence of the standard and the requirements of the Directive is included in Tables ZA.1 and ZA.2.

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 in 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 98/79/EC, 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. See EN ISO 14971, Annex ZB for the interpretation of this expression in the light of the EU Directive.

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.

Paragraph of Directive 90/385/EEC, Annex 2	Clause(s) of this European Standard	Comments/Qualifying remarks
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.
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, 5.1.1	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, 8.5.1	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, 7.5.1, 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, 8.5.1	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.

Paragraph of Directive 90/385/EEC, Annex 5	Clause(s) of this European Standard	Comments/Qualifying remarks
3.2, 3rd paragraph (c), 2nd indent	4.2, 7.5.3	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.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC (as amended)

ZB.0 General

This European Standard has been prepared under a Commission's standardization request M/023 to provide one voluntary means of conforming to requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

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.

EN ISO 13485:2016 provides requirements for a quality system applicable to medical devices. Because this standard describes a quality system that is connected in part or in whole to the conformity assessment requirements of 93/42/EEC (as amended), it is not meaningful to link individual clauses of the standard to specific Essential Requirements. Compliance with all the normative clauses in EN ISO 13485 will ensure that a process is in place to address quality system aspects related to medical devices, which are included in the conformity assessment annexes of the Directive. However, because this is an adoption of an international standard, intended to be applicable in jurisdictions all over the world, it is not the primary goal of the standard to cover exactly the European quality system requirements. Therefore, for all of the quality system requirements, conformity is not entirely achieved by complying only with the requirements specified in this standard. Manufacturers and conformity assessment bodies will need to feed the quality system requirements in the applicable Annex of the Directive into the processes provided by the standard. Explanation on the correspondence of the standard and the requirements of the Directive is included in Tables ZB.1, ZB.2 and ZB.3.

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 in 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. See EN ISO 14971, Annex ZA for the interpretation of this expression in the light of the EU Directive.

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.

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of this European Standard	Comments/Qualifying remarks
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.
3.2, 3rd paragraph (b)	4.2.2, 5.1	Covered.
3.2, 3rd paragraph (b), 1st indent	1, 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, 8.2.2, 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, 3rd paragraph (b), 3rd indent	1, 4.1, 4.2, 7.4, 8.5.1	Covered.
3.2, 3rd paragraph (c)	7.1, 7.2, 7.3	Covered.
3.2, 3rd paragraph (c), 1st indent	4.2.3, 7.2, 7.3.3, 7.3.4, 7.3.10	Covered provided that the documentation containing a general description of the medical device includes any variants.
3.2, 3rd paragraph (c), 2nd indent	4.2, 7.3.3, 7.3.4, 7.3.6, 7.3.8	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), 3rd indent	7.3.1, 7.3.6, 7.3.7, 7.3.8, 7.3.9, 7.3.10	Covered.
3.2, 3rd paragraph (c), 4th indent	7.3.2, 7.3.3, 7.3.5, 7.3.6	Covered.
3.2, 3rd paragraph (c), 5th indent	4.2.3	Covered provided that the quality management system documentation includes a statement indicating whether or not the medical device incorporates, as an integral part, a substance or a human blood derivative and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the medical device.

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of this European Standard	Comments/Qualifying remarks
3.2, 3rd paragraph (c), 6th indent	4.2.3	Covered provided that the quality management system documentation includes a statement indicating whether or not the device is manufactured utilizing tissues of animal origin as referred to in Commission Directive 2003/32/EC.
3.2, 3rd paragraph (c), 7th indent		Not covered.
3.2, 3rd paragraph (c), 8th indent	7.3.5, 7.3.8	Covered provided that the quality management system records include the pre-clinical evaluation.
3.2, 3rd paragraph (c), 9th indent		Not covered. 7.3.7 does not include the details of Annex X.
3.2, 3rd paragraph (c), 10th indent	4.1, 4.2, 7	Covered provided that the quality management system documentation includes the label and, where appropriate, instructions for use.
3.2 (d)	4.2, 7.1, 7.5, 7.6, 8.1, 8.2.3, 8.2.4	Covered.
3.2, 3rd paragraph (d), 1st indent, sterilization	4.1.1, 6.4, 7.5	Covered.
3.2, 3rd paragraph (d), 1st indent, purchasing	4.1.1, 7.4	Covered.
3.2, 3rd paragraph (d), 1st indent,	4.2, 7.1	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, 7.5.1, 7.5.9.1,, 7.6, 8.2.4	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.
6.1	4.2.4, 4.2.5	Not covered. The specific time periods in Directive are not specified.

ZB.2 Relationship with Annex V of Directive 93/42/EEC (as amended)

Compliance with this European Standard 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 — Correspondence between this European Standard and Annex V of Directive 93/42/EEC

Paragraph of Directive 93/42/EEC, Annex V	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		Not covered.
3.1 2nd paragraph 3rd indent		Not covered.
3.1 2nd paragraph 4th indent	4.1, 4.2	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 V is incorporated into the quality system documentation.
3.1 2nd paragraph 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1 2nd paragraph 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1 2nd paragraph 7th 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 8th indent 3.1 2nd paragraph 8th indent (i) 3.1 2nd paragraph 8th 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		Not covered
3.2 2nd paragraph	4.1, 4.2	Covered.
3.2 3rd paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered.
3.2 3rd paragraph (b)	4.2.2	Covered.
3.2 3rd paragraph (b) 1st indent	5.1, 5.5.1, 5.5.2	Covered.
3.2 3rd 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 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, 8.5.1	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

Paragraph of Directive 93/42/EEC, Annex V	Clause(s) of this European Standard	Comments/Qualifying remarks
		in regards to sterilization and purchasing.
3.2 3rd paragraph (c) 2nd indent	4.2, 7.5.3	Covered.
3.2 3rd paragraph (d)	7.1, 7.4.3, 7.6, 8.2.4	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.

ZB.3 Relationship with Annex VI of Directive 93/42/EEC (as amended)

Compliance with this European Standard 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 — Correspondence between this European Standard and Annex VI of Directive 93/42/EEC (as amended)

Paragraph of Directive 93/42/EEC, Annex VI	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		Not covered.
3.1, 2nd paragraph, 3rd indent		Not covered.
3.1, 2nd paragraph, 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 VI when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1, 2nd paragraph, 5th indent	4.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd paragraph, 6th indent	4.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd paragraph, 7th 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, 8th indent 3.1, 2nd paragraph, 8th indent (i) 3.1, 2nd paragraph, 8th 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.

Paragraph of Directive 93/42/EEC, Annex VI	Clause(s) of this European Standard	Comments/Qualifying remarks
3.2, 1st sentence		Not covered.
3.2, 2nd and 3rd sentences	4.1, 4.2	Covered.
3.2, 2nd paragraph, 1st indent	4.2.1, 5.1, 5.3, 5.4.1	Covered.
3.2, 2nd paragraph, 2nd indent	7.1, 7.4.3, 7.6, 8.2.4	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.
3.2, 2nd 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, 2nd paragraph, 4th indent	4.1, 4.2, 6.1	Covered.
3.2, 2nd paragraph, 5th indent	1, 4.1, 4.2, 7.4, 8.5.1	Covered.
3.2, 3rd paragraph		Not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Annex ZC
(informative)

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

ZC.0 General

This European standard has been prepared under a Commission's standardisation request, M/252, concerning the development of European standards relating to in vitro diagnostic medical devices, to provide one voluntary means of conforming to requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [OJ L 331].

Once this European Standard is cited in the Official Journal of the European Union under Directive 98/79/EC 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 ZC.1, ZC.2 and ZC.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 III, IV and VII of that Directive and associated EFTA regulations. This Annex ZC explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

EN ISO 13485:2016 provides requirements for a quality system applicable to medical devices. Because this standard describes a quality system that is connected in part or in whole to the conformity assessment requirements of 98/79/EC, it is not meaningful to link individual clauses of the standard to specific Essential Requirements. Compliance with all the normative clauses in EN ISO 13485 will ensure that a process is in place to address quality system aspects related to medical devices, which are included in the conformity assessment annexes of the Directive. However, because this is an adoption of an international standard, intended to be applicable in jurisdictions all over the world, it is not the primary goal of the standard to cover exactly the European quality system requirements. Therefore, for all of the quality system requirements, conformity is not entirely achieved by complying only with the requirements specified in this standard. Manufacturers and conformity assessment bodies will need to feed the quality system requirements in the applicable Annex of the Directive into the processes provided by the standard. Explanation on the correspondence of the standard and the requirements of the Directive is included in Tables ZC.1, ZC.2 and ZC.3.

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 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 ZC.1, ZC.2 and ZC.3 in 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 98/79/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 Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive. See EN ISO 14971, Annex ZC for the interpretation of this expression in the light of the EU Directive.

NOTE 3 This Annex ZC 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 ZC.1, ZC.2 or ZC.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.

ZC.1 Relationship with Annex III of Directive 98/79/EC

Compliance with this European Standard 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.

Table ZC.1 — Correspondence between this European Standard and Annex III of Directive 98/79/EC

Paragraph of Directive 98/79/EC, Annex III	Clause(s) of this European Standard	Comments/Qualifying remarks
3, 1st sentence		Not covered.
3, 1st indent	4.2.3, 7.2, 7.3.2, 7.3.3, 7.3.10	Covered provided that the documentation containing a general description of the medical device includes any variants.
3, 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 III when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3 below.
3, 3rd indent	4.2, 7.1, 7.3, 7.5	Covered provided quality management system documentation includes design information, including the determination of the characteristics of the basic materials, characteristics and limitation of the performance of the medical devices, methods of manufacture and, in the case of instruments, design drawings, diagrams of components, sub-assemblies, circuits and the like.
3, 4th indent		Covered provided that, in the case of devices containing tissues of human origin or substances derived from such tissue, the quality management system documentation information on the origin of such material and on the conditions in which it was collected,
3, 5th indent	4.1, 4.2	Covered provided that the quality management system documentation includes the descriptions and explanations necessary to understand the

Paragraph of Directive 98/79/EC, Annex III	Clause(s) of this European Standard	Comments/Qualifying remarks
		characteristics of the medical device drawings and diagrams and the operation of the product.
3, 6th indent	4.2, 7.3.2, 7.3.3, 7.3.6, 7.3.8	Covered provided that the quality management system documentation includes the results of the risk analysis and, where appropriate, a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if harmonized standards have not been applied in full.
3, 7th indent	6.4, 7.5.1.2, 7.5.1.3, 7.5.2	Covered.
3, 8th indent	4.2.1, 7.5.1, 7.5.9.1, 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	7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.3.7	Covered provided the applicable regulatory requirements in the design and development inputs include the essential requirements and that conformance with these essential requirements is proven in design and development verification and validation for medical devices that are combined with other medical devices in order to operate as intended.
3 10th indent	4.2.4, 8.2.4	Covered.
3, 11th indent		Covered provided that the quality management system documentation includes data from studies in a clinical or other appropriate environment or result from relevant biographical references showing adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used.
3, 12th indent	4.2.3	Covered providing the quality management system documentation includes the labels and instructions for use.
3, 13th indent	4.2	Covered provided that the quality management system records include the results of stability studies.
4, paragraph 1	1, 4–8	Covered.
4, paragraph 2, 1st indent	1, 4.2.2, 5.1, 5.5.1, 5.5.2	Covered.
4, paragraph, 2nd indent	4, 6, 7, 8	Covered.
4, paragraph, 3rd indent	4.1, 5.6, 8.2.4, 8.4, 8.5.2, 8.5.3	Covered.
5		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

Paragraph of Directive 98/79/EC, Annex III	Clause(s) of this European Standard	Comments/Qualifying remarks
		details required by the Directive including timescales for reporting.

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

Compliance with this European Standard 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 — Correspondence between this European Standard and Annex IV of Directive 98/79/EC

Paragraph of Directive 98/79/EC, Annex IV	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		Not covered.
3.1, 2nd paragraph, 3rd indent		Not covered.
3.1, 2nd paragraph, 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 IV when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1, 2nd paragraph, 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd paragraph, 6th 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 paragraph, 7th 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 sentence		Not covered.
3.2, 2nd sentence	4.1, 4.2	Covered.
3.2, 2nd paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered.
3.2, 2nd paragraph (b)	4.2.2	Covered.
3.2, 2nd paragraph (b), 1st indent	5.5.1, 5.5.2	Covered.

Paragraph of Directive 98/79/EC, Annex IV	Clause(s) of this European Standard	Comments/Qualifying remarks
3.2, 2nd paragraph (b), 2nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered.
3.2, 2nd paragraph (c), 1st indent	4.2.3, 7.2, 7.3.3, 7.3.4, 7.3.10	Covered provided that the documentation containing a general description of the medical device includes any variants.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 3rd indent	4.2, 7.1, 7.3, 7.5	Covered provided that the quality management system documentation includes design information, including the determination of the characteristics of the basic materials, characteristics and limitation of the performance of the medical devices, methods of manufacture and, in the case of instruments, design drawings, diagrams of components, sub-assemblies, circuits and the like.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 4th indent	4.1, 4.2	Covered provided that, in the case of devices containing tissues of human origin or substances derived from such tissue, the quality management system documentation information on the origin of such material and on the conditions in which it was collected.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 5th indent	4.1, 4.2	Covered provided that the quality management system documentation includes the descriptions and explanations necessary to understand the characteristics of the medical device drawings and diagrams and the operation of the product.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 6th indent	4.2, 7.3.2, 7.3.3, 7.3.6, 7.3.8	Covered provided that the quality management system documentation includes the results of the risk analysis and, where appropriate, a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if harmonized standards have not been applied in full.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 7th indent	6.4, 7.5.1.2, 7.5.2, 7.5.6	Covered.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 8th indent	4.2.1, 7.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.3, 8.2.4	Covered.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 9th indent	7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.3.7	Covered provided the applicable regulatory requirements in the design and development inputs include the essential requirements and that conformance with these essential requirements is proven in design and development verification and validation for medical devices that are combined with other medical devices in order to operate as intended.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 10th indent	4.2.4, 8.2.4	Covered.

Paragraph of Directive 98/79/EC, Annex IV	Clause(s) of this European Standard	Comments/Qualifying remarks
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 11th indent	4.1, 4.2	Covered provided that the quality management system documentation includes data from studies in a clinical or other appropriate environment or result from relevant biographical references showing adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 12th indent	4.2.3	Covered provided that the quality management system documentation includes the labels and instructions for use.
3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 13th indent	4.2	Covered provided that the quality management system records include the results of stability studies.
3.2, 2nd paragraph (d), 1st indent	6.4, 7.5	Covered.
3.2, 2nd paragraph (d), 2nd indent	7.4	Covered.
3.2, 2nd paragraph (d), 3rd indent	4.2, 7.4, 7.5,	Covered.
3.2, 2nd paragraph (e)	7.1, 7.4.3, 7.6, 8.2.4	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.

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

Compliance with this European Standard 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 — Correspondence between this European Standard and Annex VII of Directive 98/79/EC

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of this European Standard	Comments/Qualifying remarks
3.1, 1st paragraph		Not covered.
3.1, 2nd paragraph, 1st indent, reference to Annex IV, 3.1, 1st indent		Not covered.
3.1, 2nd paragraph, 1st indent, reference to Annex IV, 3.1, 2nd indent		Not covered.

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of this European Standard	Comments/Qualifying remarks
3.1, 2nd paragraph, 1st indent, reference to Annex IV, 3.1, 3rd indent		Not covered.
3.1, 2nd paragraph, 1st indent, reference to Annex IV, 3.1, 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 VII when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1, 2nd paragraph, 1st indent, reference to Annex IV, 3.1, 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd paragraph, 1st indent, reference to Annex IV, 3.1, 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered.
3.1, 2nd paragraph, 1st indent, reference to Annex IV, 3.1, 7th 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.
3.1, 2nd paragraph 2nd 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.
3.2, 1st paragraph		Not covered.
3.2, 2nd paragraph	4.1, 4.2	Covered.
3.2, 3rd paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered.
3.2, 3rd paragraph (b)	4.2.2	Covered.
3.2, 3rd paragraph (b), 1st indent	5.5.1, 5.5.2	Covered.
3.2, 3rd paragraph (b), 2nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered.
3.2, 3rd paragraph (c), 1st indent	6.4, 7.5	Covered.
3.2, 3rd paragraph (c), 2nd indent	7.4	Covered.
3.2, 3rd paragraph (c), 3rd indent	4.2, 7.4, 7.5	Covered.
3.2, 3rd paragraph (d)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 13485

Third edition
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Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition of ISO 13485 cancels and replaces the second edition (ISO 13485:2003) and ISO/TR 14969:2004, which have been technically revised. It also incorporates the Technical Corrigendum ISO 13485:2003/Cor.1:2009. A summary of the changes incorporated into this edition compared with the previous edition is given in Annex A.

Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this International Standard expects that the organization:

— identifies its role(s) under applicable regulatory requirements;

— identifies the regulatory requirements that apply to its activities under these roles;

— incorporates these applicable regulatory requirements within its quality management system.

The definitions in applicable regulatory requirements differ from nation to nation and region to region. The organization needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.

This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by the:

a) organizational environment, changes in that environment, and the influence that the organizational environment has on the conformity of the medical devices;

b) organization's varying needs;

c) organization's particular objectives;

d) product the organization provides;

e) processes the organization employs;

f) organization's size and organizational structure;

g) regulatory requirements applicable to the organization's activities.

It is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, uniformity of documentation or alignment of documentation to the clause structure of this International Standard.

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 Clarification of concepts

In this International Standard, the following terms or phrases are used in the context described below.

— When a requirement is qualified by the phrase "as appropriate", it is deemed to be appropriate unless the organization can justify otherwise. A requirement is considered appropriate if it is necessary for:

  — product to meet requirements;

  — compliance with applicable regulatory requirements;

  — the organization to carry out corrective action;

  — the organization to manage risks.

— When the term "risk" is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.

— When a requirement is required to be "documented", it is also required to be established, implemented and maintained.

— When the term "product" is used, it can also mean "service". Product applies to output that is intended for, or required by, a customer, or any intended output resulting from a product realization process.

— When the term "regulatory requirements" is used, it encompasses requirements contained in any law applicable to the user of this International Standard (e.g. statutes, regulations, ordinances or directives). The application of the term "regulatory requirements" is limited to requirements for the quality management system and the safety or performance of the medical device.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

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

0.3 Process approach

This International Standard is based on a process approach to quality management. Any activity that receives input and converts it to output can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it needs to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach."

When used within a quality management system, such an approach emphasizes the importance of:

a) understanding and meeting requirements;

b) considering processes in terms of added value;

c) obtaining results of process performance and effectiveness;

d) improving processes based on objective measurement.

0.4 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001:2008, which has been superseded by ISO 9001:2015. For the convenience of users, Annex B shows the correspondence between this International Standard and ISO 9001:2015.

This International Standard is intended to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device. This International Standard includes some particular requirements for organizations involved in the life-cycle of 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 system meets all the requirements of ISO 9001.

0.5 Compatibility with other management systems

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.

Medical devices — Quality management systems — Requirements for regulatory purposes

1 Scope

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 and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this International Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this International Standard reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of this International Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.

2 Normative references

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

ISO 9000:2015[1)], *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

1) Supersedes ISO 9000:2005.