SLOVENSKI STANDARD
SIST EN ISO 13485:2016

01-maj-2016

Nadomešča:
SIST EN ISO 13485:2012
SIST EN ISO 13485:2012/AC:2012
SIST-TP CEN ISO/TR 14969:2010

Medicinski pripomočki - Sistemi vodenja kakovosti - Zahteve za zakonodajne namene (ISO 13485:2016)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 13485:2016**

ICS:

03.100.70	Sistemi vodenja	Management systems
11.020.01	Vodenje kakovosti in ravnanje z okoljem v zdravstvu	Quality and environmental management in health care

SIST EN ISO 13485:2016 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 13485

March 2016

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.

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.

CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 13485:2016 E

Contents

Page

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.