



# SLOVENSKI STANDARD SIST EN ISO 13485:2012

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Nadomešča:

SIST EN ISO 13485:2003

SIST EN ISO 13485:2003/AC:2009

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**Medicinski pripomočki - Sistemi vodenja kakovosti - Zahteve za zakonodajne namene (ISO 13485:2003)**

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

**iTeh STANDARD PREVIEW**

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

[SIST EN ISO 13485:2012](https://standards.itih.si/catalog/standards/sist/130983fb-8036-4b12-9833-52b350f98ad9/sist-en-iso-13485-2012)

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

**Ta slovenski standard je istoveten z: EN ISO 13485:2012**

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**ICS:**

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.040.01	Medicinska oprema na splošno	Medical equipment in general

**SIST EN ISO 13485:2012**

**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 13485**

February 2012

ICS 03.120.10; 11.040.01

Supersedes EN ISO 13485:2003

English version

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

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

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

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

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

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

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

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## Foreword

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

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

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

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

This document supersedes EN ISO 13485:2003.

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

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

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

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

## EN ISO 13485:2012 (E)

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

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

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

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

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

#### Endorsement notice

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

## Annex ZA (informative)

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

#### ZA.1 General

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

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

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

- <https://standards.iteh.ai/catalog/standards/sist/b30983fb-8036-4be6-9833-52b350f98ad9/sist-en-iso-13485-2012>
- contains the necessary quality system documentation;
  - has been reviewed and approved by a Notified Body,
- and the undertakings listed in the application are correctly executed by the manufacturer.

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

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

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

## EN ISO 13485:2012 (E)

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

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



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

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

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

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

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

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

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

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## Annex ZB (informative)

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

#### ZB.1 General

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

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

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

- contains the necessary quality system documentation;
  - has been reviewed and approved by a Notified Body,
- and the undertakings listed in the application are correctly executed by the manufacturer.

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

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

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

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

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

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indent	7.3.6	the standards that will be applied.
3.2 third paragraph (c) 3 <sup>rd</sup> indent	7.3.1, 7.3.5, 7.3.6, 7.3.7	Covered
3.2 third paragraph (c) 4 <sup>th</sup> indent	7.3.2, 7.3.3, 7.3.5, 7.3.6	Covered
3.2 third paragraph (c) 5 <sup>th</sup> indent		Not covered
3.2 third paragraph (c) 6 <sup>th</sup> indent		Not covered
3.2 third paragraph (c) 7 <sup>th</sup> indent		Not covered
3.2 third paragraph (c) 8 <sup>th</sup> indent		Not covered
3.2 third paragraph (c) 9 <sup>th</sup> indent		Not covered
3.2 third paragraph (c) 10 <sup>th</sup> indent		Not covered
3.2 third paragraph (d) 1 <sup>st</sup> indent, sterilization	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (d) 1 <sup>st</sup> indent, purchasing	7.4	Covered
3.2 third paragraph (d) 1 <sup>st</sup> indent, relevant documents	4.2, 7.1 <a href="https://standards.iteh.ai/catalog/standards/sist/b30983fb-8036-4be6-9833-52b35097ad49/sist-en-iso-13485-2012">https://standards.iteh.ai/catalog/standards/sist/b30983fb-8036-4be6-9833-52b35097ad49/sist-en-iso-13485-2012</a>	Covered
3.2 third paragraph (d) 2 <sup>nd</sup> indent	4.2, 7.5.3	Covered
3.2 third paragraph (e)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

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

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

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

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