

EUROPEAN STANDARD

EN ISO 13485/A11

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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 amendment A11 modifies the European Standard EN ISO 13485:2016; it was approved by CEN on 12 April 2021.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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European foreword

This document ([EN ISO 13485:2016/A11:2021](#)) has been prepared by Technical Committee CEN/CLC/TC 3 "Quality management and corresponding general aspects for medical devices" the secretariat of which is held by NEN.

This document amends [EN ISO 13485:2016](#), incorporating corrigenda March 2016, December 2016 and 2018, with a revised European Foreword and European [Annexes ZA](#) and [ZB](#).

This Amendment to the European Standard [EN ISO 13485:2016](#) has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports requirements of EU Regulation(s).

For relationship with EU Regulation(s), see informative [Annex ZA](#), and [ZB](#), which are an integral part of this document.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of [Annex ZA](#) or [ZB](#), 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 should 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 – Correlation between normative references and dated EN and ISO standards

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

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Annex ZA (informative)

Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/575 of 14.4.2021 to provide one voluntary means of conforming to the requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in [Tables ZA.1, ZA.2 or ZA.3](#) confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Regulation, and associated EFTA regulations.

This Annex covers the relationship of this European standard with:

- the general obligations of the manufacturer in Article 10 ([Table ZA.1](#)); and,
- the quality management system requirements in the conformity assessment annexes (Annexes IX and XI) ([Table ZA.2](#) and [ZA.3](#) respectively).

[EN ISO 13485:2016](#) is an adoption of an international standard, [ISO 13485:2016](#), which is intended to be applicable in jurisdictions all over the world. Therefore, it is not the primary goal of [ISO 13485:2016](#) to cover exactly the European quality management system requirements. Consequently, for all of the quality management system requirements, conformity is not entirely achieved by complying only with the requirements specified in [EN ISO 13485](#). Manufacturers and conformity assessment bodies will need to integrate the quality management system requirements in the applicable European Regulation into the processes provided by [EN ISO 13485](#). In addition, the European Regulations require the incorporation of certain processes in the quality management system, such as clinical evaluation, risk management, post-market surveillance, and assignment of unique device identification. [EN ISO 13485](#) requires the integration of these processes into the quality management system in accordance with regulatory requirements but does not explicitly include the details of the particular European Union regulatory requirements within the standard. Furthermore, the definitions in applicable regulatory requirements differ from nation to nation and region to region. As a result, the definitions in this document can differ in wording from those in European Regulations. For use in support of European requirements, definitions in the European regulations for medical devices take precedence.

In addition to requirements on the manufacturer's quality management system, Article 10 and Annexes IX and XI of the European Regulations include a description of the regulatory processes and activities undertaken by the notified body, competent authority and European Commission, which are outside of the scope of [EN ISO 13485](#) and therefore not covered by the standard.

NOTE 1 — Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 — The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

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 Tables ZA.1, ZA.2 or ZA.3 it means that it is not addressed by this European Standard.

Table ZA.1 – Correspondence between this European standard and the requirements of Article 10 of Regulation (EU) 2017/745 [OJ L 117]

Requirements of Article 10 of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.1, 7.1, 7.2.1 c), 7.2.2 c), 7.3, 7.5	Partially covered. EN ISO 13485 includes requirements for the QMS, design and development and manufacturing that require incorporation of the regulatory requirements into the quality management system.
2	7.1	Partially covered. EN ISO 13485 includes requirements to risk management in product realization. The detail of the specific requirements of Annex 1, Chapter 1 of the Regulation is not stated explicitly.
3		Not covered. 7.3.7 of EN ISO 13485 requires clinical evaluation in accordance with applicable regulatory requirements. The details contained in Article 61 or Annex XIV are not provided.
4, 1 st paragraph	4.2.3	Partially covered. EN ISO 13485 requires that the quality management system includes one or more files either containing or referencing documents generated to demonstrate compliance with applicable regulatory requirements. A summary of the types of documents is provided. All the detail in Annexes II and III is not provided explicitly.
4, 2 nd paragraph		Not covered. Refers to action by the European Commission outside the scope of the standard.
5	4.2.3	Partially covered. EN ISO 13485 requires that the quality management system includes one or more files either containing or referencing documents generated to demonstrate compliance with applicable regulatory requirements. A summary of the types of documents is provided. All the detail in Annex XIII is not provided explicitly.
6		Not covered. Preparation of the EU declaration of conformity is not covered in EN ISO 13485
7		Not covered. 7.5.8 of EN ISO 13485 includes a requirement to control the UDI under the quality management system. The detail of the system prescribed in Article 27, and with the registration obligations referred to in Articles 29 and 31, are not provided.

Table ZA.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
8, 1 st paragraph	4.2.4, 4.2.5, 7.2.3	Partially covered. EN ISO 13485 requires the retention of documents, including records, for at least the period specified by applicable regulatory requirements. The retention time defined in the Regulations is not provided explicitly.
8, 2 nd paragraph	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term competent authority, as used in the Regulation, is not explicitly mentioned. The provision of specific information as detailed in the Regulation is not stated explicitly.
8, 3 rd paragraph		Not covered.
9, 1 st paragraph, 1 st sentence	4, 5, 6, 7, 8	Covered. EN ISO 13485 requires the quality management system to comply with applicable regulatory requirements and that production is planned, carried out, monitored and controlled to ensure that product conforms to specification and regulatory requirements.
9, 1 st paragraph, 2 nd sentence	4.1.4, 4.2.4, 5.6.2, 5.6.3, 7.3.3, 7.3.9	Partially covered. EN ISO 13485 includes general reference to regulatory requirements and standards as design and development inputs. Identification of new or revised regulatory requirements is identified as an input into Management Review) and changes needed as a result of such changes required as outputs of Management Review). Change to the medical device is covered through control of design and development changes. Common specifications are not explicitly mentioned.
9, 1 st paragraph, 3 rd sentence	4.1	Partially covered. EN ISO 13485 requires that the effectiveness of the quality management system is maintained and provides requirements for improvement processes, including corrective action and preventive action. There is no explicit requirement for the quality management system to be continually improved.
9, 2 nd paragraph	4, 5, 6, 7, 8	Covered.
9, 3 rd paragraph (a)	4.1.1, 7.3.9	Partially covered. EN ISO 13485 requires that the organization identifies applicable regulatory requirements and incorporates them in its quality management system. An explicit requirement for a documented regulatory strategy is not included. Control of design and development changes is explicitly specified.

Table ZA.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
9, 3rd paragraph (b)	4.2.3, 7.2.1c), 7.3.3b), 7.3.4a), 7.3.5	Partially covered. EN ISO 13485 includes a general reference to inclusion of applicable regulatory requirements and standards as a design input. The general safety and performance requirements, harmonized standards or common specifications are not mentioned explicitly.
9, 3rd paragraph (c)	5	Covered. EN ISO 13485 defines responsibilities of top management.
9, 3rd paragraph (d)	4.1.5, 6, 7.4.1	Covered. EN ISO 13485 includes specific requirements for provision of human resources including competence, infrastructure, work environment and contamination control.
9, 3rd paragraph (e)	4.1.2, 7.1	Partially covered. EN ISO 13485 includes requirements to apply a risk-based approach to the quality management system and apply risk management in product realization. The detail of the specific requirements of Annex 1 of the Regulation are not detailed specifically.
9, 3rd paragraph (f)		Not covered. EN ISO 13485 requires clinical evaluation in accordance with applicable regulatory requirements. The specific details in Article 61 and Annex XIV and reference to post market clinical follow-up (PMCF) are not included explicitly.
9, 3rd paragraph (g)	7.1, 7.3.2, 7.3.8, 7.5.1, 7.5.4	Covered. EN ISO 13485 requires planning product realization, planning of design and development and planning of production and service provision.
9, 3rd paragraph (h)		Not covered. EN ISO 13485 includes a requirement to control the UDI under the quality management system. The detail of the system prescribed in the Regulation is not specified explicitly.
9, 3rd paragraph (i)	8.2.1, 8.5.1	Partially covered. EN ISO 13485 requires a system of post market surveillance within the quality management system. The detail in Article 83 is not specified explicitly.
9, 3rd paragraph (j)	7.2.3	Partially covered. EN ISO 13485 specifies requirements for communication with customers and regulatory authorities. The term 'regulatory authorities' is used in a general context and the terms competent authority and notified body, as used in the Regulation, are not explicitly mentioned. Other economic operators and other stakeholders are not explicitly mentioned.
9, 3rd paragraph (k)	8.2.2, 8.2.3, 8.3.3	Partially covered. EN ISO 13485 requires processes for reporting events in accordance with applicable regulatory requirements. The details of the vigilance system and the timescales for reporting are not specified explicitly.

Table ZA.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
9, 3 rd paragraph (l)	8.5.2, 8.5.3	Covered. EN ISO 13485 specifies requirements for management of corrective actions and preventive actions, including verification of their effectiveness.
9, 3 rd paragraph (m)	8.2.5, 8.2.6, 8.4, 8.5	Covered. EN ISO 13485 includes requirements on monitoring and measurement of processes, analysis of data and improvement of product.
10	8.2.1, 8.5.1	Partially covered. EN ISO 13485 requires a system of post market surveillance in accordance with regulatory requirements within the quality management system. The detail in Article 83 is not covered explicitly.
11	4.2.3a), 7.3.3, 7.5.1e)	Partially covered. EN ISO 13485 includes a general requirement for design inputs to include applicable regulatory requirements and for the medical device file to include the labelling, including instructions for use. Specific requirements of Chapter III of Annex I are not explicitly included nor is the language in which the information is to be provided. The physical characteristics of the information on the label are not covered explicitly.
12	7.2.3, 8.2.2d), 8.2.3, 8.3.3	Partially covered. EN ISO 13485 uses the definitions in ISO 9000 where this situation would be within the definition of a correction rather than a corrective action. Communication with customers and regulatory authorities is required. The term 'regulatory authorities' is used in a general context and the terms competent authority and notified body, as used in the Regulation, are not explicitly mentioned. Distributors as a specific category of customer, and importers and authorized representative are not explicitly mentioned.
13	8.2.3	Partially covered. EN ISO 13485 includes the requirements on adverse event reporting and mentions actions in the field to be reported. The detailed requirements in Articles 87 and 88 are not specified explicitly.
14, 1 st paragraph	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term competent authority, as used in the Regulation, is not explicitly mentioned. The provision of information as in the Regulation, the language in which it is to be provided, the provision of samples of the device free of charge or granting access to the device are not covered explicitly.

Table ZA.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
14, 2 nd , 3 rd and 4 th paragraphs		Not covered. Refers to actions of the competent authority outside the scope of the standard.
15	4.1, 4.2.3, 7.2.3, 7.4	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The provision of information on the identity of a third party that designed or manufactured the medical device as in the Regulation are not covered explicitly.
16		Not covered.

Table ZA.2 – Correspondence between this European standard and the requirements of Annex IX of Regulation (EU) 2017/745 [OJ L 117]

Requirements of Annex IX of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.1	Partially covered. EN ISO 13485 requires the quality management system to comply with applicable regulatory requirements. EN ISO 13485 is applicable to all sizes of organization and all types and class of medical device. EN ISO 13485 does not have requirements for the quality management system to be subject to third party assessment or certification.
2.1, 1 st sentence		Not covered.
2.1, bullet 1		Not covered.
2.1, bullet 2	4.2	Covered. EN ISO 13485 requires that the quality management system documentation includes information on the device(s) within its scope.
2.1, bullet 3		Not covered.
2.1, bullet 4		Not covered.
2.1, bullet 5	4.2	Covered. EN ISO 13485 specifies the quality management system documentation and how it is controlled.
2.1, bullet 6	4.2, 5.1	Partially covered. EN ISO 13485 requires evidence of top management commitment to implementing the quality management system. EN ISO 13485 does not explicitly require a documented undertaking.
2.1, bullet 7	4.1.4, 4.2, 5.1, 5.4.2, 5.6, 6.1, 8	Covered. EN ISO 13485 requires that the quality management system is applied and maintained.
2.1, bullet 8	8.2.1, 8.5.1	Partially covered. EN ISO 13485 references inclusion of applicable regulatory requirements on post market surveillance into the quality management system. The detailed requirements in the Regulation and to post-market clinical follow-up are not referenced explicitly.

Table ZA.2 (continued)

Requirements of Annex IX of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.1, bullet 9	8.2.1, 8.5.1	Partially covered. EN ISO 13485 references inclusion of applicable regulatory requirements on post market surveillance into the quality management system. The detailed requirements in the regulation and post-market clinical follow-up are not referenced explicitly.
2.1, bullet 10		Not covered. EN ISO 13485 requires clinical evaluation in accordance with planned and documented arrangements and applicable regulatory requirements. A clinical evaluation plan is not referenced explicitly.
2.1, bullet 11		Not covered.
2.2, 1 st paragraph	4.1, 4.2, 5, 6, 8	Partially covered. EN ISO 13485 requires that the quality management system is implemented systematically in accordance with the requirements of the standard and applicable regulatory requirements. EN ISO 13485 requires a quality manual, written policies and procedures, quality planning and quality records.
2.2, 2 nd paragraph (a)	4.2.1a), 5.1c), 5.3c), 5.4.1, 7.1a)	Covered. EN ISO 13485 requires that quality objectives are defined and documented.
2.2, 2 nd paragraph (b) indent 1	5.5.1	Covered. EN ISO 13485 requires that organizational structures, roles and responsibilities, and interrelationships are defined and documented.
2.2, 2 nd paragraph (b) indent 2	5.6, 7.3.5, 8.1, 8.2.1, 8.2.4, 8.2.5, 8.2.6, 8.3, 8.4,	Covered. EN ISO 13485 includes requirements on monitoring the operation of the quality management system and the control of non-conforming product.
2.2 2 nd paragraph (b) indent 3	4.1.5, 7.4.1	Covered. EN ISO 13485 has requirements for cases when an organization outsources an activity, and these requirements link with the requirements for evaluation and selection of suppliers, their monitoring and their re-evaluation.
2.2 2 nd paragraph (b) indent 4		Not covered.
2.2, 2 nd paragraph (c)	4.2.5, 7.3,	Covered. EN ISO 13485 covers design and development controls as well as the control of documentation, including records.
2.2, 2 nd paragraph (c) indent 1	4.1.1, 7.3.9	Partially covered. EN ISO 13485 requires that the organization identifies applicable regulatory requirements and incorporates them in its quality management system. An explicit requirement for a documented regulatory strategy is not included. Control of design and development changes is explicitly specified.

Table ZA.2 (continued)

Requirements of Annex IX of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.2, 2 nd paragraph (c) indent 2	7.2.1c), 7.3.3	Partially covered. EN ISO 13485 includes a general reference to inclusion of applicable regulatory requirements and standards as a design input. The general safety and performance requirements, harmonized standards or common specifications are not mentioned explicitly.
2.2, 2 nd paragraph (c) indent 3	4.1.2, 7.1	Partially covered. EN ISO 13485 includes requirements to apply a risk-based approach to the quality management system and apply risk management in product realization. The detail of the specific requirements of Annex 1 of the Regulation are not detailed specifically.
2.2, 2 nd paragraph (c) indent 4		Not covered. EN ISO 13485 requires clinical evaluation in accordance with applicable regulatory requirements. The specific details in Article 61 and Annex XIV and reference to post market clinical follow-up (PMCF) are not included explicitly.
2.2, 2 nd paragraph (c) indent 5	7.3	Partially covered. EN ISO 13485 details requirements for design and development verification and validation. Preclinical evaluation as an aspect of design verification is not mentioned explicitly.
2.2, 2 nd paragraph (c) indent 6	4.2.3a), 7.3.3b), 7.5.1e)	Partially covered. EN ISO 13485 includes a general requirement for design inputs to include applicable regulatory requirements and for the medical device file to include the labelling, including instructions for use. Specific requirements of Chapter III of Annex I are not included explicitly.
2.2, 2 nd paragraph (c) indent 7	7.5.8, 7.5.9	Covered. EN ISO 13485 specifies requirements for identification and traceability.
2.2, 2 nd paragraph (c) indent 8	4.1.4, 4.2.4, 5.6.2, 5.6.3, 7.3.3, 7.3.9	Partially covered. EN ISO 13485 includes general reference to regulatory requirements and standards as design and development inputs. Identification of new or revised regulatory requirements is identified as an input into Management Review and changes needed as a result of such inputs are required as outputs of Management Review. Change to the medical device is covered through control of design and development changes.
2.2, 2 nd paragraph (d).	7.5.1, 7.5.5, 7.5.6, 7.5.7	Covered. EN ISO 13485 covers controls in product realization including sterilization.
2.2, 2 nd paragraph (e).	7.4.3, 7.5.1, 7.5.9, 7.6, 8.2.5, 8.2.6	Covered. EN ISO 13485 covers monitoring and measurement of product and the calibration of test equipment.

Table ZA.2 (continued)

Requirements of Annex IX of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.2 3 rd paragraph	7.2.3,	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. The provision of specific information as detailed in the Regulation is not detailed explicitly.
2.4	4.1.4, 7.2.3	Partially covered. EN ISO 13485 requires incorporation of regulatory requirements into the QMS and communication with regulatory authorities in accordance with regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. Communication in relation to changes in the QMS or range of medical devices is not referred to specifically.
3.2	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. The provision of specific information as detailed in the Regulation is not detailed explicitly.

Table ZA.3 – Correspondence between this European standard and the requirements of Annex XI of Regulation (EU) 2017/745 [OJ L 117]

Requirements of Annex XI of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
4	4.1, 5.1, 8.2.6	Partially covered. EN ISO 13485 has requirements for the implementation of the quality management system and final verification. EN ISO 13485 does not have requirements for the quality management system to be subject to third party assessment or certification.
5		Not covered.
6.1, 1 st sentence		Not covered.
6.1, bullet 1		See Table ZA.2 , 2.1.
6.1, bullet 2	4.2.3	Partially covered. EN ISO 13485 requires that the quality management system includes one or more files either containing or referencing documents generated to demonstrate compliance with applicable regulatory requirements. A summary of the types of documents is provided. All the detail in Annexes II and III is not provided explicitly.
6.1, bullet 3.		Not covered.

Table ZA.3 (*continued*)

Requirements of Annex XI of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
6.2, 1 st paragraph	4.1	Partially covered. EN ISO 13485 requires that the quality management system is implemented systematically in accordance with the requirements of the standard and applicable regulatory requirements. EN ISO 13485 requires a quality manual, written policies and procedures, quality planning and quality records. EN ISO 13485 does not explicitly reference conformance to an approved type-examination certificate.
6.2, 2 nd paragraph, reference to Annex IX, 2.2 (a)	4.2.1a), 5.1c), 5.3c), 5.4.1, 7.1a)	Covered. EN ISO 13485 requires that quality objectives are defined and documented.
6.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 1	5.5.1	Covered. EN ISO 13485 requires that organizational structures, roles and responsibilities, and interrelationships are defined and documented.
6.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 2	5.6, 7.3.5, 8.1, 8.2.1, 8.2.4, 8.2.5, 8.2.6, 8.3, 8.4,	Covered. EN ISO 13485 includes requirements on monitoring the operation of the quality management system and the control of non-conforming product.
6.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 3	4.1.5, 7.4.1	Covered. EN ISO 13485 has requirements for cases when an organization outsources an activity, and these requirements link with the requirements for evaluation and selection of suppliers, their monitoring and their re-evaluation.
6.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 4		Not covered.
6.2, 2 nd paragraph, reference to Annex IX, 2.2 (d)	7.5.1, 7.5.5, 7.5.6, 7.5.7	Covered. EN ISO 13485 covers controls in product realization including sterilization.
6.2, 2 nd paragraph, reference to Annex IX, 2.2 (e)	7.4.3, 7.5.1, 7.6, 8.2.5, 8.2.6	Covered. EN ISO 13485 covers monitoring and measurement of product and the calibration of test equipment.
6.4	4.1.4, 7.2.3	Partially covered. EN ISO 13485 requires incorporation of regulatory requirements into the QMS and communication with regulatory authorities in accordance with regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. Communication in relation to changes in the QMS or range of medical devices is not referred to specifically.
7, 1 st paragraph	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. The provision of specific information as detailed in the Regulation is not detailed explicitly.

Table ZA.3 (continued)

Requirements of Annex XI of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
12, 1 st paragraph	4.2.1, 4.2.3, 4.2.4, 4.2.5, 6, 7.1, 7.4, 7.5, 7.6, 8.2.5, 8.2.6, 8.3, 8.5	Covered. EN ISO 13485 covers controls of documents, infrastructure, product realization including sterilization, nonconformity and corrective action.
12, 2 nd paragraph		See all of 6 and 7 in this table above.
13	8.2.1, 8.5.1	Partially covered. EN ISO 13485 references inclusion of applicable regulatory requirements on post market surveillance into the quality management system. The detailed requirements in the regulation are not referenced explicitly.

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 product(s) falling within the scope of this standard.

Annex ZB

(informative)

Relationship between this European standard and the requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/575 of 14.4.2021 to provide one voluntary means of conforming to the requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in [Tables ZB.1, ZB.2 or ZB.3](#) confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Regulation, and associated EFTA regulations.

This Annex covers the relationship of this European standard with:

- the general obligations of the manufacturer in Article 10 ([Table ZB.1](#)); and,
- the quality management system requirements in the conformity assessment annexes (Annexes IX and XI) ([Table ZB.2](#) and [ZB.3](#) respectively).

[EN ISO 13485:2016](#) is an adoption of an international standard, [ISO 13485:2016](#), which is intended to be applicable in jurisdictions all over the world. Therefore, it is not the primary goal of [ISO 13485:2016](#) to cover exactly the European quality management system requirements. Consequently, for all of the quality management system requirements, conformity is not entirely achieved by complying only with the requirements specified in [EN ISO 13485](#). Manufacturers and conformity assessment bodies will need to integrate the quality management system requirements in the applicable European Regulation into the processes provided by [EN ISO 13485](#). In addition, the European Regulations require the incorporation of certain processes in the quality management system, such as clinical evaluation, risk management, post-market surveillance, and assignment of unique device identification. [EN ISO 13485](#) requires the integration of these processes into the quality management system in accordance with regulatory requirements but does not explicitly include the details of the particular European Union regulatory requirements within the standard. Furthermore, the definitions in applicable regulatory requirements differ from nation to nation and region to region. As a result, the definitions in this document can differ in wording from those in European Regulations. For use in support of European requirements, definitions in the European regulations for medical devices take precedence.

In addition to requirements on the manufacturer's quality management system, Article 10 and Annexes IX and XI of the European Regulations include a description of the regulatory processes and activities undertaken by the notified body, competent authority and European Commission, which are outside of the scope of [EN ISO 13485](#) and therefore not covered by the standard.

NOTE 1 — Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be 'reduced as far as possible', 'reduced to a level as low as reasonably practicable', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'prevented' or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 — The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

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 [Tables ZB.1](#), [ZB.2](#) or [ZB.3](#) it means that it is not addressed by this European Standard.

Table ZB.1 – Correspondence between this European standard and Article 10 of Regulation (EU) 2017/746 [OJ L 117]

Requirements of Article 10 of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.1, 7.1, 7.2.1c), 7.2.2c), 7.3, 7.5.	Partially covered. EN ISO 13485 includes requirements for the QMS, design and development and manufacturing that require incorporation of the regulatory requirements into the quality management system.
2	7.1	Partially covered. EN ISO 13485 includes requirements to risk management in product realization. The detail of the specific requirements of Annex 1, Chapter 1 of the Regulation is not stated explicitly
3		Not covered. 7.3.7 of EN ISO 13485 requires performance evaluation in accordance with applicable regulatory requirements. The details contained in Article 56 and Annex XIII are not provided.
4, first paragraph	4.2.3	Partially covered. EN ISO 13485 requires that the quality management system includes one or more files either containing or referencing documents generated to demonstrate compliance with applicable regulatory requirements. A summary of the types of documents is provided. All the detail in Annexes II and III is not provided explicitly.
4, second paragraph		Not covered.
5		Not covered. Preparation of the EU declaration of conformity and affixing the CE mark is not covered in EN ISO 13485 .
6		Not covered. 7.5.8 of EN ISO 13485 includes a requirement to control the UDI under the quality management system. The detail of the system prescribed in the Article 24, and with the registration obligations referred to in Articles 26 and 28, are not provided.
7, 1 st paragraph	4.2.4, 4.2.5, 7.2.3	Partially covered. EN ISO 13485 requires the retention of documents, including records, for at least the period specified by applicable regulatory requirements. The retention time defined in the Regulations is not provided explicitly.
7, 2 nd paragraph	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term competent authority, as used in the Regulation, is not explicitly mentioned. The provision of specific information as detailed in the Regulation is not stated explicitly.
7, 3 rd paragraph		Not covered.

Table ZB.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
8, 1 st paragraph, 1 st sentence	4, 5, 6, 7, 8	Covered. EN ISO 13485 requires the quality management system to comply with applicable regulatory requirements and that production is planned, carried out, monitored and controlled to ensure that product conforms to specification and regulatory requirements.
8, 1 st paragraph, 2 nd sentence	4.1.4, 4.2.4, 5.6.2, 5.6.3, 7.3.3, 7.3.9	Partially covered. EN ISO 13485 includes general reference to regulatory requirements and standards as design and development inputs. Identification of new or revised regulatory requirements is identified as an input into Management Review and changes needed as a result of such inputs are required as outputs of Management Review. Change to the medical device is covered through control of design and development changes. Common specifications are not explicitly mentioned.
8, 1 st paragraph, 3 rd sentence	4.1	Partially covered. EN ISO 13485 requires that the effectiveness of the quality management system is maintained and provides requirements for improvement processes, including corrective action and preventive action. There is no explicit requirement for the quality management system to be continually improved.
8, 2 nd paragraph	4, 5, 6, 7, 8	Covered.
8, 3 rd paragraph (a)	4.1.1, 7.3.9	Partially covered. EN ISO 13485 requires that the organization identifies applicable regulatory requirements and incorporates them in its quality management system. An explicit requirement for a documented regulatory strategy is not included. Control of design and development changes is explicitly specified.
8, 3 rd paragraph (b)	4.2.3, 7.2.1c), 7.3.3b), 7.3.4a), 7.3.5	Partially covered. EN ISO 13485 includes a general reference to inclusion of applicable regulatory requirements and standards as a design input. The general safety and performance requirements, harmonized standards or common specifications are not mentioned explicitly.
8, 3 rd paragraph (c)	5	Covered. EN ISO 13485 defines responsibilities of top management.
8, 3 rd paragraph (d) first element, resource management	6	Covered. EN ISO 13485 includes specific requirements for provision of human resources including competence, infrastructure, work environment and contamination control.
8, 3 rd paragraph (d) second element, suppliers and subcontractors	4.1.5, 7.4.1	Covered. EN ISO 13485 includes requirements on the evaluation and selection of suppliers, their monitoring and their re-evaluation.

Table ZB.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
8, 3 rd paragraph (e)	4.1.2, 7.1	Partially covered. EN ISO 13485 includes requirements to apply a risk-based approach to the quality management system and apply risk management in product realization. The detail of the specific requirements of Annex 1 of the Regulation are not detailed specifically
8, 3 rd paragraph (f)		Not covered. EN ISO 13485 requires performance evaluation in accordance with applicable regulatory requirements. The specific details in Article 56 and Annex XIV and reference to post market performance follow-up (PMPF) are not included explicitly.
8, 3 rd paragraph (g)	7.1, 7.3.2, 7.3.8, 7.5.1, 7.5.4	Covered. EN ISO 13485 requires planning product realization, planning of design and development and planning of production and service provision.
8, 3 rd paragraph (h)		Not covered. EN ISO 13485 includes a requirement to control the UDI under the quality management system. The detail of the system prescribed in the Regulation is not specified explicitly.
8, 3 rd paragraph (i)	8.2.1, 8.5.1	Partially covered. EN ISO 13485 requires a system of post market surveillance within the quality management system. The detail in Article 78 is not specified explicitly.
8, 3 rd paragraph (j)	7.2.3	Partially covered. EN ISO 13485 specifies requirements for communication with customers and regulatory authorities. The term 'regulatory authorities' is used in a general context and the terms competent authority and notified body, as used in the Regulation, are not explicitly mentioned. Other economic operators and other stakeholders are not explicitly mentioned.
8, 3 rd paragraph (k)	8.2.2, 8.2.3, 8.3.3	Partially covered. EN ISO 13485 requires processes for reporting events in accordance with applicable regulatory requirements. The details of the vigilance system and the timescales for reporting are not specified explicitly.
8, 3 rd paragraph (l)	8.5.2, 8.5.3	Covered. EN ISO 13485 specifies requirements for management of corrective actions and preventive actions, including verification of their effectiveness.
8, 3 rd paragraph (m)	8.2.5, 8.2.6, 8.4, 8.5	Covered. EN ISO 13485 includes requirements on monitoring and measurement of processes, analysis of data and improvement of product.
9	8.2.1, 8.5.1	Partially covered. EN ISO 13485 requires a system of post market surveillance in accordance with regulatory requirements within the quality management system. The detail in Article 78 is not covered explicitly.

Table ZB.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
10	4.2.3a) 7.3.3, 7.5.1e)	Partially covered. EN ISO 13485 includes a general requirement for design inputs to include applicable regulatory requirements and for the medical device file to include the labelling, including instructions for use. Specific requirements of Annex I are not explicitly included nor is the language in which the information is to be provided. The physical characteristics of the information on the label are not covered explicitly.
11, 1 st paragraph	7.2.3, 8.3.3	Partially covered. EN ISO 13485 uses the definitions in ISO 9000 where this situation would be within the definition of a correction rather than a corrective action. Communication with customers and regulatory authorities is required. The term 'regulatory authorities' is used in a general context and the terms competent authority and notified body, as used in the Regulation, are not explicitly mentioned. Distributors as a specific category of customer, and importers and authorized representative are not explicitly mentioned.
11, 2 nd paragraph	8.2.2d), 8.2.3, 8.3.3	Partially covered. EN ISO 13485 uses the definitions in ISO 9000 where this situation would be within the definition of a correction rather than a corrective action. Communication with regulatory authorities is required in accordance with regulatory requirements. Specific regulatory bodies are not stated explicitly.
12	8.2.3	Partially covered. EN ISO 13485 includes the requirements on adverse event reporting and mentions actions in the field to be reported. The detailed requirements in Articles 82 and 83 are not specified explicitly.
13, 1 st paragraph	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term competent authority, as used in the Regulation, is not explicitly mentioned. The provision of information as in the Regulation, the language in which it is to be provided, the provision of samples of the device free of charge or granting access to the device are not covered explicitly.
13, 2 nd , 3 rd and 4 th paragraphs		Not covered.

Table ZB.1 (continued)

Requirements of Article 10 of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
14	4.1, 4.2.3, 7.2.3, 7.4	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The provision of information on the identity of a third party that designed or manufactured the medical device as in the Regulation are not covered explicitly.
15		Not covered.

Table ZB.2 – Correspondence between this European standard and Annex IX of Regulation (EU) 2017/746 [OJ L 117]

Requirements of Annex IX of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.1	Partially covered. EN ISO 13485 requires the quality management system to comply with applicable regulatory requirements. EN ISO 13485 is applicable to all sizes of organization and all types and class of medical device. EN ISO 13485 does not have requirements for the quality management system to be subject to third party assessment or certification.
2.1, 1 st sentence		Not covered.
2.1, bullet 1		Not covered.
2.1, bullet 2,	4.2	Covered. EN ISO 13485 requires that the quality management system documentation includes information on the device(s) within its scope.
2.1, bullet 3,		Not covered.
2.1, bullet 4		Not covered.
2.1, bullet 5,	4.2	Covered. EN ISO 13485 specifies the quality management system documentation and how it is controlled.
2.1, bullet 6,	4.2, 5.1	Partially covered. EN ISO 13485 requires evidence of top management commitment to implementing the quality management system. EN ISO 13485 does not explicitly require a documented undertaking.
2.1, bullet 7	4.1.4, 4.2, 5.1, 5.4.2, 5.6, 6.1, 8	Covered. EN ISO 13485 requires that the quality management system is applied and maintained.
2.1, bullet 8	8.2.1, 8.5.1	Partially covered. EN ISO 13485 references inclusion of applicable regulatory requirements on post market surveillance into the quality management system. The detailed requirements in the Regulation to post-market performance follow-up are not referenced explicitly.

Table ZB.2 (continued)

Requirements of Annex IX of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.1, bullet 9	8.2.1, 8.5.1	Partially covered. EN ISO 13485 references inclusion of applicable regulatory requirements on post market surveillance into the quality management system. The detailed requirements in the regulation and post-market performance follow-up are not referenced explicitly.
2.1, bullet 10		Not covered. EN ISO 13485 requires performance evaluation in accordance with planned and documented arrangements and applicable regulatory requirements. A performance evaluation plan is not referenced explicitly.
2.1, bullet 11		Not covered. EN ISO 13485 requires that the continued suitability of the medical device is maintained. A performance evaluation plan is not referenced explicitly.
2.2, 1 st paragraph	4.1, 4.2, 5, 6, 8	Partially covered. EN ISO 13485 requires that the quality management system is implemented systematically in accordance with the requirements of the standard and applicable regulatory requirements. EN ISO 13485 requires a quality manual, written policies and procedures, quality planning and quality records.
2.2, 2 nd paragraph (a)	4.2.1a), 5.1c), 5.3c), 5.4.1, 7.1a)	Covered. EN ISO 13485 requires that quality objectives are defined and documented.
2.2, 2 nd paragraph (b) indent 1	5.5.1	Covered. EN ISO 13485 requires that organizational structures, roles and responsibilities, and interrelationships are defined and documented.
2.2, 2 nd paragraph (b) indent 2	5.6, 7.3.5, 8.1, 8.2.1, 8.2.4, 8.2.5, 8.2.6, 8.3, 8.4	Covered. EN ISO 13485 includes requirements on monitoring the operation of the quality management system and the control of non-conforming product.
2.2, 2 nd paragraph (b) indent 3	4.1.5, 7.4	Covered. EN ISO 13485 has requirements when an organization outsources an activity which link with the requirements for evaluation and selection of suppliers, their monitoring and their re-evaluation.
2.2, 2 nd paragraph (b) indent 4		Not covered.
2.2, 2 nd paragraph (c)	4.2.5, 7.3,	Covered. EN ISO 13485 covers design and development controls as well as the control of documentation, including records.
2.2, 2 nd paragraph (c) indent 1	4.1.1, 7.3.9	Partially covered. EN ISO 13485 requires that the organization identifies applicable regulatory requirements and incorporates them in its quality management system. An explicit requirement for a documented regulatory strategy is not included. Control of design and development changes is explicitly specified.

Table ZB.2 (continued)

Requirements of Annex IX of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.2, 2 nd paragraph (c) indent 2	7.2.1c), 7.3.3	Partially covered. EN ISO 13485 includes a general reference to inclusion of applicable regulatory requirements and standards as a design input. The general safety and performance requirements, harmonized standards or common specifications are not mentioned explicitly.
2.2, 2 nd paragraph (c) indent 3	4.1.2, 7.1	Partially covered. EN ISO 13485 includes requirements to apply a risk-based approach to the quality management system and apply risk management in product realization. The detail of the specific requirements of Annex 1 of the Regulation are not detailed specifically.
2.2, 2 nd paragraph (c) indent 4		Not covered. EN ISO 13485 requires performance evaluation in accordance with applicable regulatory requirements. The specific details in Article 56 and Annex XIV and reference to post market performance follow-up (PMPF) are not included explicitly.
2.2, 2 nd paragraph (c) indent 5	7.3.4, 7.3.6, 7.3.7	Partially covered. EN ISO 13485 details requirements for design and development verification and validation. Preclinical evaluation as an aspect of design verification is not mentioned explicitly.
2.2, 2 nd paragraph (c) indent 6	4.2.3a) 7.3.3b), 7.5.1e)	Partially covered. EN ISO 13485 includes a general requirement for design inputs to include applicable regulatory requirements and for the medical device file to include the labelling, including instructions for use. Specific requirements of Chapter III of Annex I are not included explicitly.
2.2, 2 nd paragraph (c) indent 7	7.5.8, 7.5.9	Covered. EN ISO 13485 specifies requirements for identification and traceability.
2.2, 2 nd paragraph (c) indent 8	4.1.4, 4.2.4, 5.6.2, 5.6.3, 7.3.3, 7.3.9	Partially covered. EN ISO 13485 includes general reference to regulatory requirements and standards as design and development inputs. Identification of new or revised regulatory requirements is identified as an input into Management Review and changes needed as a result of such inputs are required as outputs of Management Review. Change to the medical device is covered through control of design and development changes.
2.2, 2 nd paragraph (d)	7.5.1, 7.5.5, 7.5.6, 7.5.7	Covered. EN ISO 13485 covers controls in product realization including sterilization.
2.2, 2 nd paragraph (e)	7.4.3, 7.5.1, 7.5.9, 7.6, 8.2.5, 8.2.6	Covered. EN ISO 13485 covers monitoring and measurement of product and the calibration of test equipment.

Table ZB.2 (continued)

Requirements of Annex IX of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
2.2, 3 rd paragraph	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. The provision of specific information as detailed in the Regulation is not detailed explicitly.
2.4	4.1.4, 7.2.3	Partially covered. EN ISO 13485 requires incorporation of regulatory requirements into the QMS and communication with regulatory authorities in accordance with regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. Communication in relation to changes in the QMS or range of medical devices is not referred to specifically.
3.2	7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. The provision of specific information as detailed in the Regulation is not detailed explicitly.

Table ZB.3 – Correspondence between this European standard and Annex XI of Regulation (EU) 2017/746 [OJ L 117]

Requirements of Annex XI of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.1, 5.1, 8.2.6	Partially covered. EN ISO 13485 has requirements for the implementation of the quality management system and final verification. EN ISO 13485 does not have requirements for the quality management system to be subject to third party assessment or certification.
2		Not covered. Preparation of the EU declaration of conformity and affixing the CE mark is not covered in EN ISO 13485 .
3.1, 1 st paragraph		Not covered.
3.1, 2 nd paragraph, bullet 1		See Table ZB.3, section 2.1
3.1, 2 nd paragraph, bullet 2	4.2.3	Partially covered. EN ISO 13485 requires that the quality management system includes one or more files either containing or referencing documents generated to demonstrate compliance with applicable regulatory requirements. A summary of the types of documents is provided. All the detail in Annexes II and III is not provided explicitly.
3.1, 2 nd paragraph, bullet 3		Not covered.

Table ZB.3 (continued)

Requirements of Annex XI of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
3.2, 1 st paragraph	4.1	Partially covered. EN ISO 13485 requires that the quality management system is implemented systematically in accordance with the requirements of the standard and applicable regulatory requirements. EN ISO 13485 requires a quality manual, written policies and procedures, quality planning and quality records. EN ISO 13485 does not explicitly reference conformance to an approved type-examination certificate.
3.2, 2 nd paragraph, reference to Annex IX, 2.2 (a)	4.2.1a), 5.1c), 5.3c), 5.4.1, 7.1a)	Covered. EN ISO 13485 requires that quality objectives are defined and documented.
3.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 1	5.5.1	Covered. EN ISO 13485 requires that organizational structures, roles and responsibilities, and interrelationships are defined and documented.
3.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 2	5.6, 7.3.5, 8.1, 8.2.1, 8.2.4, 8.2.5, 8.2.6, 8.3, 8.4,	Covered. EN ISO 13485 includes requirements on monitoring the operation of the quality management system and the control of non-conforming product.
3.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 3	4.1.5, 7.4.1	Covered. EN ISO 13485 has requirements for cases when an organization outsources an activity, and these requirements link with the requirements for evaluation and selection of suppliers, their monitoring and their re-evaluation.
3.2, 2 nd paragraph, reference to Annex IX, 2.2 (b), indent 4		Not covered.
3.2, 2 nd paragraph, reference to Annex IX, 2.2 (d)	7.5.1, 7.5.5, 7.5.6, 7.5.7	Covered. EN ISO 13485 covers controls in product realization including sterilization.
3.2, 2 nd paragraph, reference to Annex IX, 2.2 (e)	7.4.3, 7.5.1, 7.6, 8.2.5, 8.2.6	Covered. EN ISO 13485 covers monitoring and measurement of product and the calibration of test equipment.
6, bullet 1		Not covered.
6, bullet 2, reference to Annex IX, 2.1 bullet 5	4.2	Covered. EN ISO 13485 specifies the quality management system documentation and how it is controlled.
6, bullet 3		Not covered.
6, bullet 4, reference to Annex IX, 2.4	4.1.4, 7.2.3	Partially covered. EN ISO 13485 requires incorporation of regulatory requirements into the QMS and communication with regulatory authorities in accordance with regulatory requirements. The term 'regulatory authorities' is used in a general context and the term notified body, as used in the Regulation, is not explicitly mentioned. Communication in relation to changes in the QMS or range of medical devices is not referred to specifically.
6, bullet 5		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 product(s) falling within the scope of this standard.