



BSI Standards Publication

**Guidance on the relationship between
EN ISO 13485: 2016 (Medical devices – Quality
management systems – Requirements for regulatory
purposes) and European Medical Devices Regulation
and In Vitro Diagnostic Medical Devices Regulation**

National foreword

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English version

**Guidance on the relationship between EN ISO 13485: 2016
(Medical devices - Quality management systems -
Requirements for regulatory purposes) and European
Medical Devices Regulation and In Vitro Diagnostic
Medical Devices Regulation**

Document d'orientation sur la relation entre l'EN ISO
13485: 2016 (Dispositifs médicaux - Systèmes de
management de la qualité - Exigences à des fins
réglementaires) et le Règlement européen relatif aux
dispositifs médicaux ainsi que le Règlement relatif aux
dispositifs médicaux de diagnostic in vitro

Leitfaden zum Zusammenhang zwischen EN ISO
13485: 2016 (Medizinprodukte -
Qualitätsmanagementsysteme - Anforderungen für
regulatorische Zwecke) und den europäischen
Verordnungen über Medizinprodukte und In-vitro-
Diagnostika

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**CEN-CENELEC Management Centre:
Rue de la Science 23, B-1040 Brussels**

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European Foreword

This document (CEN/TR 17223:2018) has been prepared by Technical Committee CEN/CLC/JTC 3, “Quality management and corresponding general aspects for medical devices”, the secretariat of which is held by NEN.

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

Introduction

This Technical Report has been prepared to provide guidance on the relationship between EN ISO 13485:2016 (*Medical devices – Quality management systems – Requirements for regulatory purposes*) and the requirements in the European Regulations on Medical Devices (MDR)- Regulation (EU) 2017/745 - and *in vitro* Diagnostic Medical Devices (IVDR) -Regulation (EU) 2017/746.

EN ISO 13485 describes a quality management system that is applicable to medical devices and is intended for regulatory purposes. The European Regulations for medical devices and EN ISO 13485 present holistic requirements for systematic application of a process approach to quality management into which an organization can incorporate regulatory requirements that are applicable to its activities. As the requirements are integrated and build on each other, all the requirements applicable to the organizations' activities and the applicable regulatory requirements need to be applied. It is not intended that requirements are implemented in isolation from the complete system. While this Technical Report describes the interrelationship of individual paragraphs, or parts of a paragraph, of the Regulations with particular subclauses of EN ISO 13485, this is not intended to imply that these subclauses can be implemented in the absence of the entire quality management system described in the standard.

This Technical Report focuses on the general obligations of the manufacturer (Article 10) and the conformity assessment requirements (Annexes IX and XI) of the European Regulations for Medical Devices and *in vitro* Diagnostic Medical Devices. Compliance with all the normative clauses in EN ISO 13485 will ensure that a process is in place to address quality management system aspects related to medical devices, which are included in Article 10 and Annexes IX and XI of the Regulations.

Generally, it is not meaningful to link individual clauses of EN ISO 13485 to specific general safety and performance requirements (Annex I). The General Requirements in Chapter 1 of Annex 1, however, relate to the application of risk and the requirements for the manufacturer to implement a risk management system. As the general obligation of the manufacturer in Article 10 requires the implementation of a risk management system and EN ISO 13485 requires processes for risk management in product realization, the relationships between Chapter 1 in the general safety and performance requirements and the corresponding subclauses of EN ISO 13485:2016 are included in this Technical Report. Specific details of a risk management system for medical devices are provided in EN ISO 14971.

The scope of EN ISO 13485 indicates that the standard can be applied by:

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

As such, EN ISO 13485 may be applied by other economic operators in the supply chain such as authorized representatives, importers, distributors or assemblers of systems or procedure packs. Consequently, EN ISO 13485 can also support meeting the regulatory obligations for authorized representatives (Article 11), Importers (Article 13), Distributors (Article 14) or assemblers of systems or procedure packs (MDR Article 22).

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 management system requirements. Therefore, 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 feed the quality management system requirements in the applicable European Regulation into the processes provided by EN ISO 13485.

For example, Article 15 of the European Regulations define specific requirements for a position of 'person responsible for regulatory compliance'. While this position is not explicitly mentioned in EN ISO 13485, it constitutes a regulatory requirement that would need to be incorporated into the quality management system of an organization seeking to comply with the Regulations. Once incorporated into the quality management system, related requirements, for example for competence, definition of responsibilities and interrelationships, would apply to this position.

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.

Explanation on the relationship between the requirements of EN ISO 13485 and:

- European Regulations on Medical Devices (Regulation (EU) 2017/745) is provided in this Technical Report in Table 1; and,
- European Regulations on *in vitro* Diagnostic Medical Devices (Regulation (EU) 2017/746) is provided in this Technical Report in Table 2.

NOTE 1 When a requirement does not appear in Table 1 or Table 2, it means that it is not addressed by EN ISO 13485:2016.

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 2 In many places, Annex XI of the European regulations refers back to paragraphs in Annex IX. In Tables 1 and 2, the applicable text from Annex IX is incorporated under the reference for Annex XI.

Article 8 of the European Regulations (Use of harmonized standards), indicates that system or process requirements to be fulfilled by economic operators, such as requirements for quality management systems, are to be presumed to be fulfilled if the system or process is in conformance with a relevant harmonized standard. A standard is given the status of being harmonized by publication of a reference in the Official Journal of the European Union under European Regulations for Medical Devices and *in vitro* Diagnostic Medical Devices. For a harmonized standard, presumption of conformity with the identified requirements of these Regulations is provided by compliance with the normative clauses given in the table or tables in the Annex Z of a standard, within the limits of the scope of the standard, once that standard has been implemented as a national standard in at least one Member State. The Annex Z explains to which requirements, under

which conditions and to what extent, presumption of conformity can be claimed. Inclusion of a standard in the Official Journal of the European Union and the preparation, agreement and publication of an Annex Z requires a mandate being given to a European Standards Body by the European Commission.

In advance of such a mandate, this Technical Report has been prepared to provide guidance to manufacturers and conformity assessment bodies on the relationship between EN ISO 13485:2016 and the European Regulations for Medical Devices and *in vitro* Diagnostic Medical Devices. This Technical Report does not imply that compliance with EN ISO 13485 provides a presumption of conformity with the requirements of the European Regulations for Medical Devices or *in vitro* Diagnostic Medical Devices.

1 Scope

This Technical Report provides guidance on the relationship between EN ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes* and the requirements in EU Regulation 2017/745 on Medical Devices and EU Regulation 2017/746 on *in vitro* Diagnostic Medical Devices.

2 Normative references

The following referenced document is indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

For the purposes of this Technical Report, the terms and definitions in EN ISO 13485 apply.

4 Relationship between the European Regulations for Medical Devices and *in vitro* Diagnostic Medical Devices and the clauses of EN ISO 13485

Table 1 shows the relationship between the clauses of EN ISO 13485 and the requirements of the European Regulations on Medical Devices (Regulation (EU) 2017/745), together with commentary on the extent to which the requirements of the standard cover the specific details in the Regulation.

Table 2 shows the relationship between the clauses of EN ISO 13485 and the requirements of the European Regulations on *in vitro* Diagnostic Medical Devices (Regulation (EU) 2017/746), together with commentary on the extent to which the requirements of the standard cover the specific details in the Regulation.

Following the content of this Technical Report does not infer compliance with the specific quality management system requirements of the European Regulations; it serves as tool for understanding the links and connection between EN ISO 13485 and the European Regulations.

Table 1 — The relationship between the clauses of EN ISO 13485 and the requirements of the European Regulations on Medical Devices (EU Regulation 2017/745) Article 10, Annex 1 Chapter 1, Annex IX and Annex XI

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
1.	When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.			4.1, 7.1, 7.2.1 c), 7.2.2 c), 7.3, 7.5	Covered. EN ISO 13485 includes requirements for the QMS, design and development and manufacturing that require incorporation of regulatory requirements into the quality management system.
		Annex I, Chapter 1, 1.	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	7.1, 7.3, 7.5	Partially covered. EN ISO 13485 includes requirements to apply risk management in product realization. The detail of the specific requirements of Annex 1, Chapter 1 of the Regulation is not stated explicitly. EN ISO 14971:2012 Medical devices - Application of Risk Management is referenced in a NOTE and listed in the Bibliography of EN ISO 13485.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
2.	Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.			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.
		Annex I, Chapter 1, 2.	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.		Not 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, Chapter 1 of the Regulation is not stated explicitly. EN ISO 14971:2012 Medical devices - Application of Risk Management is referenced in a NOTE and listed in the Bibliography of EN ISO 13485.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
		Annex I Chapter I, 3	Manufacturers shall establish, implement, document and maintain a risk management system.	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.
			Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:	4.1.2, 7.1	Partially covered. EN ISO 13485 includes requirements to apply risk management in product realization. The detail of the specific requirements of Annex 1, Chapter 1 of the Regulation is not stated explicitly. EN ISO 14971:2012 Medical devices - Application of Risk Management is referenced in a NOTE and listed in the Bibliography of EN ISO 13485.
			(a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring		Not covered

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
			during, the intended use and during reasonably foreseeable misuse; (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;		
			(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability;	8.2.1, 7.3.9	Partially covered. EN ISO 13485 requires a documented procedure for the production and post-product phase into the risk management system.
			(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.		Not covered
		Annex I Chapter I, 4.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks,		Not covered

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
			Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (a) eliminate or reduce risks as far as possible through safe design and manufacture; (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and (c) provide information for safety (warnings/precautions/contraindications) and, where appropriate, training to users.		Partially covered. EN ISO 13485 requires the identification and provision of user training and information necessary for safe use.
			Manufacturers shall inform users of any residual risks.		Not covered
		Annex I Chapter I, 5.	In eliminating or reducing risks related to use error, the manufacturer shall: (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	7.2.1b), d), 7.2.2d), 7.3.4d)	Partially covered. EN ISO 13485 identifies usability as a specific design and development input. Design and development inputs link directly to design and development outputs and requirements for verification and validation.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
			(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	7.2.1b), 7.2.2d)	Partially covered. EN ISO 13485 requires the identification and provision of user training.
		Annex 1, Chapter I, 6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	4.2.4, 4.2.5, 7.2.1, 7.3.6, 7.3.7, 7.5.11	Partially covered. EN ISO 13485 requires the definition of the lifetime of the medical device and identification of delivery and post-delivery activities necessary for the intended use.
		Annex 1, Chapter I, 7.	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	4.2.3c), 7.5.11	Partially covered. EN ISO 13485 requires protection during processing, storage, handling and distribution.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
		Annex 1, Chapter I, 8	All known and foreseeable risks, and any undesirable side-effects, shall be minimized and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.		Not covered.
		Annex 1, Chapter I, 9.	For the devices referred to in Annex XVI [Products without an intended medical purpose], the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.		Not covered.
3. MDR	Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.			7.3.7	Partially covered. EN ISO 13485 requires clinical evaluation in accordance with applicable regulatory requirements. The details contained in Article 61 or Annex XIV are not provided explicitly.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
4. MDR	Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.			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.
		Annex XI, Part A, 6.1, bullet 2. Annex XI, Part B, 12, Paragraph 2	the technical documentation referred to in Annexes II and III for the types approved,		
	The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III.				Not applicable to EN ISO 13485. Pertinent to European Commission.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
5.	Manufacturers of custom-made devices shall draw up, keep up to date and keep available for competent authorities, documentation in accordance with Section 2 of Annex XIII.			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.	Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20.				Not covered. Preparation of the EU declaration of conformity and affixing the CE mark is not covered in EN ISO 13485.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
		Annex XI, Part A, 5	When the manufacturer fulfils the obligations laid down in [Annex XI] Section 4, it shall draw up and keep an EU declaration of conformity in accordance with Article 19 and Annex IV for the device covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure and to declare that the device concerned conforms to the type described in the EU type-examination certificate and meets the requirements of this Regulation which apply to the device.		Not covered. Preparation of the EU declaration of conformity and affixing the CE mark is not covered in EN ISO 13485.
7.	Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.			7.5.8	Partially covered. 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 explicitly
8.	Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate,			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

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
	including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.				regulatory requirements. The retention time defined in the Regulations is not provided explicitly.
	Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.			7.2.3	Partially covered. EN ISO 13485 requires communication with regulatory authorities in accordance with applicable regulatory requirements. The provision of specific information as detailed in the Regulation is not stated explicitly.
	A manufacturer with a registered place of business outside the Union shall, in order to allow its authorized representative to fulfil the tasks mentioned in Article 11(3), ensure that				Not covered

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
	the authorized representative has the necessary documentation permanently available.				
9.	Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation.			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.
	Changes in device design or characteristics and changes in the harmonized standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner.	Annex IX 2.2 paragraph 2 c) indent 8	management of design or quality management system changes;	4.1.4, 4.2.4, 7.3.9	Partially covered. EN ISO 13485 includes general reference to regulatory requirements and standards as design and development inputs (7.3.3). Identification of new or revised regulatory requirements is identified as an input into Management Review (5.6.2) and changes needed as a result of such changes required as outputs of Management Review (5.6.3). Change to the medical device is covered through 7.3.9 (Control of

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
					design and development changes). Common specifications are not explicitly mentioned.
		Annex IX, 2.4	The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered.	4.1.4, 7.2.3	Partially covered. EN ISO 13485 requires incorporation of regulatory requirements into the QMS and communication with regulatory authorities, including Notified Bodies, in accordance with regulatory requirements but does not specifically refer to communication in relation to changes in the QMS or range of medical devices.
	Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk			1, 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.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
	class and the type of device.	Annex IX, Chapter 1, 1.	1. The manufacturer shall establish, document and implement a quality management system as described in Article 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2 and shall be subject to audit, as laid down in Sections 2.3 and 2.4, and to surveillance as specified in Section 3.	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.
		Annex IX, Chapter 1, 2.2.	Implementation of the quality management system shall ensure compliance with this Regulation. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.	1, 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.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
		Annex XI, 4	The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall carry out a final verification, as specified in Section 6, and shall be subject to the surveillance referred to in Section 7.	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.
		Annex XI, Part A, 6.2, paragraph 1. Annex XI, Part B, 12, Paragraph 2	Implementation of the quality management system shall be such as to ensure that there is compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to the devices at each stage. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.	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.

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
	The quality management system shall cover all parts and elements of a manufacturer's organization dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.			1, 4, 5, 6, 7, 8	Partially covered. EN ISO 13485 provides a framework to act as the basis for incorporating regulatory requirements into an organization's quality management system and demonstrating compliance with the Regulations. The organization has to identify and incorporate applicable regulatory requirements within that framework.
		Annex IX, Chapter 1, 2.1. Annex XI, Part A, 6.1, bullet 1. Annex XI, Part B, 12, Paragraph 1	2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body		Not covered
		Annex XI, Part A, 6.1, bullet 3. Annex XI, Part B, 12, Paragraph 1	The application shall include: a copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the		Not covered

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
			application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.		
		Annex IX, Chapter 1, 2.1 bullet 1. Annex XI, Part A, 6.1, bullet 1. Annex XI, Part B, 12, Paragraph 1	The application shall include: the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorized representative, the name of the authorized representative and the address of the authorized place of business,		Not covered. EN ISO 13485 requires documentation of the scope of the quality management system. The name and address of the registered business and the authorized representative, if applicable, are not detailed explicitly
		Annex IX, Chapter 1, 2.1 bullet 2. Annex XI, Part A, 6.1, bullet 1. Annex XI, Part B, 12, Paragraph 1	all relevant information on the device or group of devices covered by the quality management system,	4.2	Covered. EN ISO 13485 requires that the quality management system documentation includes information on the device(s) within its scope.
		Annex IX, Chapter 1, 2.1 Bullet 3.	a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous		Not covered

MDR Article 10 reference	MDR Article 10 text	MDR Annex reference	MDR Annex text	ISO 13485 reference	Comments
		Annex XI, Part A, 6.1, bullet 1. Annex XI, Part B, 12, Paragraph 1	application for the same device- related quality management system,		
		Annex IX, Chapter 1, 2.1 Bullet 4	a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure,		Not covered
		Annex IX, Chapter 1, 2.1 Bullet 5. Annex XI, Part A, 6.1, bullet 1. Annex XI, Part B, 12, Paragraph 1	the documentation on the manufacturer's quality management system,	4.2	Covered. EN ISO 13485 specifies the quality management system documentation and how it is controlled.
		Annex IX, Chapter 1, 2.1, Bullet 6. Annex XI, Part A, 6.1, bullet 1. Annex XI, Part B, 12,	a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures	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.