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**Navodilo za povezavo med EN ISO 13485: 2016 (Medicinski pripomočki - Sistemi vodenja kakovosti - Zahteve za zakonodajne namene) ter Uredbo (EU) o medicinskih pripomočkih in Uredbo (EU) o in vitro diagnostičnih medicinskih pripomočkih**



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



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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# 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

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



This draft Technical Report is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/CLC/JTC 3.



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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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## European Foreword

This document (FprCEN/TR 17223:2017) 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.

This document is currently submitted to the Vote on TR.

# 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 13485describes 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 of the general safety and performance requirements 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 obligations for quality management systems 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 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.

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 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, 7.3, 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. | | 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.<br>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, Section 3 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, Section 3 of the Regulation is not stated explicitly.<br>EN ISO 14971:2012 Medical devices - Application of Risk Management is referenced in a NOTE and listed in the Bibliography of EN ISO 13485. |
| | | Annex I | Manufacturers shall establish, | 7.1 | Partially covered. |

| MDR Article 10 reference | MDR Article 10 text | MDR Annex reference | MDR Annex text | ISO 13485 reference | Comments |
|---|---|---|---|---|---|
| | | Chapter I, 3 | implement, document and maintain a risk management system. | | EN ISO 13485 includes requirements to risk management in product realization. The detail of the specific requirements of Annex 1, Section 3 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 of the Regulation is not stated explicitly.<br>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;<br>(b) identify and analyse the known and foreseeable hazards associated with each device;<br>(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; | | Not covered |

| MDR Article 10 reference | MDR Article 10 text | MDR Annex reference | MDR Annex text | ISO 13485 reference | Comments |
|---|---|---|---|---|---|
| | | | (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; | | |
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| | | | (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, | Partially covered. EN ISO 13485 requires a document procedure to feedback information from 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 | | Not covered |

| MDR Article 10 reference | MDR Article 10 text | MDR Annex reference | MDR Annex text | ISO 13485 reference | Comments |
|---|---|---|---|---|---|
| | | | conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.<br>In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:<br>(a) eliminate or reduce risks as far as possible through safe design and manufacture;<br>(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/contra-indications) and, where appropriate, training to users. | 7.2.1b), d), 7.2.2d), 7.3.4d) | 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:<br>(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 | 7.3.3a) | Partially covered. EN ISO 13485 identifies usability as a specific design and development input. Design and development inputs link directly to design |

| MDR Article 10 reference | MDR Article 10 text | MDR Annex reference | MDR Annex text | ISO 13485 reference | Comments |
|---|---|---|---|---|---|
| | | | (design for patient safety), and | | and development outputs and requirements for verification and validation. |
| | | | (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 | 4.2.3.c, 7.5.11 | Partially covered. EN ISO 13485 requires protection during processing, storage, handling and distribution. |