



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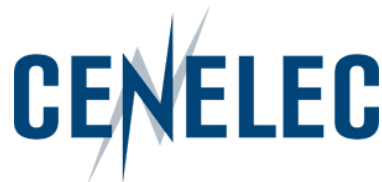
**Guidance on the relationship between EN ISO 13485: 2016
(Medical devices - Quality management systems -
Requirements for regulatory purposes) and European
Medical Devices Regulation and In Vitro Diagnostic
Medical Devices Regulation**

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

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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.