

STN	Zdravotnícke pomôcky. Systémy manažérstva kvality. Požiadavky na splnenie predpisov (ISO 13485: 2016).	STN EN ISO 13485 85 5001
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Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/16

Rozpracované prekladom.

Obsahuje: EN ISO 13485:2016, ISO 13485:2016

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EUROPEAN STANDARD

EN ISO 13485

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2016

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Supersedes EN ISO 13485:2012

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)

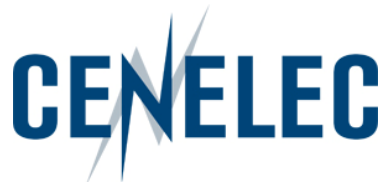
Medizinprodukte - Qualitätsmanagementsysteme -
Anforderungen für regulatorische Zwecke (ISO
13485:2016)

This European Standard was approved by CEN on 30 January 2016.

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Contents	Page
European foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC (as amended)	5
Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC (as amended)	10
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC	17

European foreword

This document (EN ISO 13485:2016) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

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

This document supersedes EN ISO 13485:2012.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directives, see informative Annex ZA, ZB and ZC, which are integral parts of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, ZB and ZC, 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 shall 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 1 — Correlation between normative references and dated EN and ISO standards

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

Endorsement notice

The text of ISO 13485:2016 has been approved by CEN as EN ISO 13485:2016 without any modification.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN