SVENSK STANDARD
SS-EN ISO 13485:2016/A11:2021

Medicintekniska produkter – Ledningssystem för kvalitet – Krav för regulatoriska ändamål (ISO 13485:2016)

Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)

Svenska Institutet för Standarder

Language: engelska/English

Edition: 1

Svenska Institutet för Standarder

Den här standarden kan hjälpa dig att effektivisera och kvalitetssäkra ditt arbete. SIS har fler tjänster att erbjuda dig för att underlätta tillämpningen av standarder i din verksamhet.

SIS Abonnemang
Snabb och enkel åtkomst till gällande standard med SIS Abonnemang, en prenumerationstjänst genom vilken din organisation får tillgång till all världens standarder, senaste uppdateringarna och där hela din organisation kan ta del av innehållet i prenumerationen.

Utbildning, event och publikationer
Vi erbjuder även utbildningar, rådgivning och event kring våra mest sålda standarder och frågor kopplade till utveckling av standarder. Vi ger också ut handböcker som underlättar ditt arbete med att använda en specifik standard.

Vill du delta i ett standardiseringsprojekt?
Genom att delta som expert i någon av SIS 300 tekniska kommittéer inom CEN (europeisk standardisering) och/eller ISO (internationell standardisering) har du möjlighet att påverka standardiseringsarbetet i frågor som är viktiga för din organisation. Välkommen att kontakta SIS för att få veta mer!

Kontakt
Skriv till kundservice@sis.se, besök sis.se eller ring 08 - 555 523 10

Upplysningar om sakinnehållet i standarden lämnas av Svenska institutet för standarder, telefon 08 - 555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Standarden är framtagen av kommittén för Medicintekniska kvalitetssystem, SIS/TK 355.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

Fastställd: 2021-09-13
ICS: 03.100.70; 03.120.10; 04.080; 11.040.01; 11.110.10

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Europastandarden EN ISO 13485:2016/A11:2021 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 13485:2016/A11:2021.

The European Standard EN ISO 13485:2016/A11:2021 has the status of a Swedish Standard. This document contains the official version of EN ISO 13485:2016/A11:2021.

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LÄSANVISNINGAR FÖR STANDARDER

I dessa anvisningar behandlas huvudprinciperna för hur regler och yttre begränsningar anges i standardiseringsprodukter.

Krav
Ett krav är ett uttryck i ett dokuments innehåll som anger objektivt verifierbara kriterier som ska uppfyllas och från vilka ingen avvikelse tillåts om efterlevnad av dokumentet ska kunna åberopas. Krav uttrycks med hjälpverbet **ska** (eller **ska inte** för förbud).

Rekommendation
En rekommendation är ett uttryck i ett dokuments innehåll som anger en valmöjlighet eller ett tillvägagångssätt som bedöms vara särskilt lämpligt utan att nödvändigtvis nämna eller utesluta andra. Rekommendationer uttrycks med hjälpverbet **bör** (eller **bör inte** för avrådanden).

Instruktion
Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

Förklaring
En förklaring är ett uttryck i ett dokuments innehåll som förmedlar information. En förklaring kan uttrycka tillåtelse, möjlighet eller förmåga. Tillåtelse uttrycks med hjälpverbet **får**. Inom standardiseringen saknas rekommenderad nekande motsats till hjälpverbet får, förbud uttrycks med **ska inte** enligt reglerna för krav. Möjlighet och förmåga uttrycks med hjälpverbet **kan** (eller motsatsen **kan inte**).

READING INSTRUCTIONS FOR STANDARDS

These instructions cover the main principles for the use of provisions and external constraints in standardization deliverables.

Requirement
A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary **shall** (or **shall not** for prohibition).

Recommendation
A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary **should** (or **should not** for dissuasion).

Instruction
An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

Statement
A statement is an expression, in the content of a document, that conveys information. A statement can express permission, possibility or capability. Permission is expressed by the auxiliary **may**. There is no recommended opposite expression for the auxiliary may in standardization, prohibition is expressed by the use of **shall not** in accordance with the rules for requirements. Possibility and capability are expressed by the auxiliary **can** (its opposite being **cannot**).

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485/A11

September 2021

ICS 03.100.70; 11.040.01

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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Ref. No. EN ISO 13485:2016/A11:2021: E

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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	**Equivalent dated standard**	
as listed in Clause 2 of the ISO standard	**EN**	**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, 1st 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, 2nd 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, 1st 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, 2nd 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, 3rd paragraph		Not covered.
9, 1st paragraph, 1st 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, 1st paragraph, 2nd 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, 1st paragraph, 3rd 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, 2nd paragraph	4, 5, 6, 7, 8	Covered.