SLOVENSKI STANDARD
SIST EN ISO 13485:2003/AC:2009

01-december-2009

Nadomeġļ a:
SIST EN ISO 13485:2003/AC:2008

Medicinski pripomoļ ki - Sistemi vodenja kakovosti - Zahteve za zakonodajne namene (ISO 13485:2003/Cor 1:2009)

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003/Cor 1:2009)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2003/Cor 1:2009)

Dispositifs médicaux - Systèmes de manegement de la qualité - Exigences à des fins réglementaires (ISO 13485:2003/Cor 1:2009)

Ta slovenski standard je istoveten z: **EN ISO 13485:2003/AC:2009**

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 13485:2003/AC:2009 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485:2003/AC

August 2009
Août 2009
August 2009

ICS 03.120.10; 11.040.01

English version
Version Française
Deutsche Fassung

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003/Cor 1:2009)

Dispositifs médicaux - Systèmes de manegement de la qualité - Exigences à des fins réglementaires (ISO 13485:2003/Cor 1:2009)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2003/Cor 1:2009)

This corrigendum becomes effective on 26 August 2009 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 26 août 2009 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 26. August 2009 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

CEN Management Centre:
Avenue Marnix 17, B-1000 Brüssel

CENELEC Central Secretariat:
Avenue Marnix 17, B-1000 Brüssel

Modifications following EN ISO 13485:2003/AC:2007

1 Modification to the title page

Add the following reference to the superseding note:

“EN 46003:1999”

2 Modification to the 2nd paragraph

Replace with the following:

"This European Standard supersedes EN 46003:1999, EN ISO 13485:2000 and EN ISO 13488:2000."

3 Modification to the 3rd paragraph

Replace "July 2006" *with"* July 2009"

4 Modification to the 7th paragraph

Replace the first sentence with the following:

"Three of the modules cited in Council decision, i.e. modules E, D and H require that "*the manufacturer must operate an approved quality system*".

Add the following first dash to the existing two:

"- Final product inspection and testing (module E),"

5 Modification to the 8th paragraph

Replace twice in the first and second sentences "modules D or H" *with* "modules E, D or H".

6 Modification to the 9th paragraph

To be deleted.

7 Modification to the table

Replace the table with the following:

Module D	Module E	Module H
Permissible exclusions	Permissible exclusions for conformity of "product quality assurance"	Permissible exclusions

Sub-clause 7.3: design and development	Sub-clause 7.3: design and development Sub-clause 7.5.1: control of production and service provision Sub-clause 7.5.2: validation of processes for production and service provision	NO exclusions permitted
Module D is the basis for annex V of 93/42/EEC Directive and the basis for annex VII of 98/79/EC Directive. Module E is the basis for annex VI of Directive 93/42/EEC. Module H is the basis for annex 2 of Directive 90/385/EEC, for annex II of Directive 93/42/EEC and for annex IV of Directive 98/79/EC.		

8 Modification to the endorsement notice

Delete the note.

9 Modification to Annex ZA

Replace Annex ZA with the following:

"Annex ZA

(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."

10 Modification to Annex ZB

Replace Annex ZB with the following:

"Annex ZB

(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."

11 Addition of a new Annex ZC

Add new Annex ZC:

"Annex ZC

(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 98/79/EC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."

Modification following EN ISO 13485:2003/AC:2009

Endorsement notice

The text of ISO 13485:2003/Cor.1:2009 has been approved by CEN as a European Corrigendum without any modification.

INTERNATIONAL STANDARD ISO 13485:2003
TECHNICAL CORRIGENDUM 1

Published 2009-08-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Medical devices — Quality management systems — Requirements for regulatory purposes

TECHNICAL CORRIGENDUM 1

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 13485:2003 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices.*

Pages v and vi, Introduction, subclauses 0.3 and 0.4

Replace “ISO 9001” with “ISO 9001:2000” throughout both subclauses.

Page 1, Scope, subclause 1.1

Replace “ISO 9001” with “ISO 9001:2000” throughout the subclause.

Page 25, Annex B, first paragraph

Replace “ISO 9001” with “ISO 9001:2000” throughout the entire paragraph, including the numbered list.

ICS 03.120.10; 11.040.01 **Ref. No. ISO 13485:2003/Cor.1:2009(E)**

Published in Switzerland