
Medicinski pripomočki - Sistemi vodenja kakovosti - Zahteve za zakonodajne namene - Tehnični popravek (ISO 13485:2003+Cor 1:2009)

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

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

Dispositifs médicaux - Systèmes de management de la qualité - Exigences à des fins réglementaires - Rectificatif technique 1 (ISO 13485:2003+Cor 1:2009)

[https://standards.iteh.ai/catalog/standards/sist/fce67489-e668-4413-a63b-](https://standards.iteh.ai/catalog/standards/sist/fce67489-e668-4413-a63b-23161930b69c/sist-en-iso-13485-2012-ac-2012)

Ta slovenski standard je istoveten z: EN ISO 13485:2012/AC:2012

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 13485:2012/AC:2012 **en**

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EUROPEAN STANDARD

EN ISO 13485:2012/AC

NORME EUROPÉENNE

July 2012

EUROPÄISCHE NORM

Juillet 2012

Juli 2012

ICS 03.120.10; 11.040.01

English version
Version Française
Deutsche Fassung

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

Dispositifs médicaux - Systèmes de
management de la qualité - Exigences à
des fins réglementaires - Rectificatif
technique 1 (ISO 13485:2003+Cor 1:2009)

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

This corrigendum becomes effective on 4 July 2012 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 4 juillet 2012 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 4. Juli 2012 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.



**CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels**

EN ISO 13485:2012/AC:2012 (E)

1 Modification to the Title

The title of EN ISO 13485:2012 has to be corrected as such:

"Medical devices — Quality management systems — Requirements for regulatory purposes — Technical Corrigendum 1 (ISO 13485:2003+Cor 1:2009)".

2 Modification to ZC.4, Relationship with Annex VII of Directive 98/79/EC

Replace Table ZC.3 with the following one:

"

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1 st indent, reference to Annex IV, 3.1, 1 st indent		Not covered
3.1 second paragraph 1 st indent, reference to Annex IV, 3.1, 2 nd indent		Not covered
3.1 second paragraph 1 st indent, reference to Annex IV, 3.1, 3 rd indent		Not covered
3.1 second paragraph 1 st indent, reference to Annex IV, 3.1, 4 th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex VII unless the explicit legal requirements of the Directive are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 1 st indent, reference to Annex IV, 3.1, 5 th indent		Not covered
3.1 second paragraph 1 st indent, reference to Annex IV, 3.1, 6 th indent		Not covered
3.1 second paragraph 1 st indent, reference to		Not covered

Annex IV, 3.1, 7 th indent		
3.1 second paragraph 2 nd indent		Not covered
3.2 first paragraph		Not covered
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2	Covered
3.2 third paragraph (b) 1 st indent	5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2 nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 third paragraph (c) 1 st indent	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (c) 2 nd indent	7.4	Covered
3.2 third paragraph (c) 3 rd indent	4.2, 7.5.1, 7.5.2, 7.4	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

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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

iTeh STANDARD PREVIEW

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

[SIST EN ISO 13485:2012/AC:2012](https://standards.iteh.ai/catalog/standards/sist/fce67489-e668-4413-a63b-23161930b69c/sist-en-iso-13485-2012-ac-2012)

<https://standards.iteh.ai/catalog/standards/sist/fce67489-e668-4413-a63b-23161930b69c/sist-en-iso-13485-2012-ac-2012>

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)

ISO 13485:2003/Cor.1:2009(E)

Pages 25 to 56, Annex B, table, right-hand column

Replace “ISO 9001” with “ISO 9001:2000” in the right-hand column (entitled “ISO 13485:2003”) throughout the entire table.

Page 57, Bibliography

Replace

“[6] ISO 13641:2002, *Elimination or reduction of risk of infection related to in vitro diagnostic medical devices*”

with

“[6] EN 13641:2002, *Elimination or reduction of risk of infection related to in vitro diagnostic reagents*”.

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[SIST EN ISO 13485:2012/AC:2012](https://standards.iteh.ai/catalog/standards/sist/fee67489-e668-4413-a63b-23161930b69c/sist-en-iso-13485-2012-ac-2012)

<https://standards.iteh.ai/catalog/standards/sist/fee67489-e668-4413-a63b-23161930b69c/sist-en-iso-13485-2012-ac-2012>