EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485:2012/AC

July 2012
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.

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Ref. No. EN ISO 13485:2012:EN ISO 13485:2012/AC:2012 D/E/F

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 1st indent, reference to Annex IV, 3.1, 1st indent		Not covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 2nd indent		Not covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 3rd indent		Not covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 4th 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 1st indent, reference to Annex IV, 3.1, 5th indent		Not covered
3.1 second paragraph 1st indent, reference to Annex IV, 3.1, 6th indent		Not covered
3.1 second paragraph 1st indent, reference to		Not covered

Annex IV, 3.1, 7th indent		
3.1 second paragraph 2nd 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) 1st indent	5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 third paragraph (c) 1st indent	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (c) 2nd indent	7.4	Covered
3.2 third paragraph (c) 3rd 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.

".

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.

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Published in Switzerland

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*”.