INTERNATIONAL STANDARD ISO 13485:2003
TECHNICAL CORRIGENDUM 1

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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)**

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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*”.