06-01-2017

Medicinsk udstyr – Kvalitetsledelses-systemer – Krav angående opfyldelse af lovmæssige formål

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

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ICS: 03.120.10; 11.040.01

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NORME EUROPÉENNE
December 2016

EUROPÄISCHE NORM
Décembre 2016
Dezember 2016

ICS 03.100.70; 11.040.01

English version
Version Française
Deutsche Fassung

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 corrigendum becomes effective on 21 December 2016 for incorporation in the official English version of the EN.

Ce corrigendum prendra effet le 21 décembre 2016 pour incorporation dans la version anglaise officielle de la EN.

Die Berichtigung tritt am 21. Dezember 2016 zur Einarbeitung in die offizielle Englische Fassung der EN in Kraft.

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

1 Modification to the European foreword

The fourth sentence now reads:

"This document supersedes EN ISO 13485:2012 and CEN ISO/TR 14969:2005."

2 Modification to Annex ZA

The title of the Annex ZA now reads:

"Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 90/385/EEC (as amended)"

The first paragraph now reads:

"This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Union and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 90/385/EEC (as amended) on active implantable medical devices."

The third paragraph has been deleted.

The first sentence of Note 1, now reads:

"NOTE 1 Where a reference from a clause of this European Standard to the risk management process is made, the risk management process needs to be in compliance with Directive 90/385/EEC, as amended by 2007/47/EC."

The last sentence of Note 2 has been deleted.

In Table ZA.1, several cross references have been corrected, e.g. the ones corresponding to:

— *3.2, 3rd paragraph (b)*

— *3.2 3rd paragraph (b) 3rd indent*

— *3.2, 3rd paragraph (e)*

In Table ZA.2, several cross references have been corrected, e.g. the ones corresponding to:

— *3.2, 3rd paragraph (b), 3rd indent*

— *3.2, 3rd paragraph (c), 2nd indent*

In the last paragraph, the warnings 1 and 2 have been grouped under the following warning:

WARNING: The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 90/385/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

3 Modification to Annex ZB

The title of the Annex ZB now reads:

"Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 93/42/EEC (as amended)"

The first paragraph now reads:

"This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Union and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 93/42/EEC (as amended) on medical devices."

The third paragraph has been deleted.

The last sentence of Note 2 has been deleted.

In Table ZB.1, several cross references have been corrected, e.g. the ones corresponding to:

— *3.2, 3rd paragraph (b), 2nd indent*

— *3.2, 3rd paragraph (b), 3rd indent*

— *3.2, 3rd paragraph (d)*

— *3.2, 3rd paragraph (e)*

In Table ZB.2, several cross references have been corrected, e.g. the ones corresponding to:

— *3.2 3rd paragraph (b) 2nd indent*

— *3.2 3rd paragraph (b) 3rd indent*

— *3.2 3rd paragraph (c) 2nd indent*

— *3.2 3rd paragraph (d)*

In Table ZB.3, several cross references have been corrected, e.g. the ones corresponding to:

— *3.2, 2nd paragraph, 2nd indent*

— *3.2, 2nd paragraph, 3rd indent*

— *3.2, 2nd paragraph, 5th indent*

In the last paragraph, the warnings 1 and 2 have been grouped under the following warning:

WARNING: The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 93/42/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

4 Modification to Annex ZC

The title of the Annex ZC now reads:

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

The first paragraph now reads:

"This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Union and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices."

The third paragraph has been deleted.

The last sentence of Note 2 has been deleted.

In Table ZC.1, several cross references have been corrected, e.g. the ones corresponding to:

— *3, 1st indent*

— *3, 4th indent*

— *3, 7th indent*

— *3, 8th indent*

— *3 10th indent*

— *3, 11th indent*

— *3, 12th indent*

— *4, paragraph 2, 1st indent*

In Table ZC.2, several cross references have been corrected, e.g. the ones corresponding to:

— *3.2, 2nd paragraph (b), 2nd indent*

— *3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 7th indent*

— *3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 8th indent*

— *3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 10th indent*

— *3.2, 2nd paragraph (e)*

In Table ZC.3, several cross references have been corrected, e.g. the ones corresponding to:

— *3.2, 3rd paragraph (b), 2nd indent*

— *3.2, 3rd paragraph (d)*

In the last paragraph, the warnings 1 and 2 have been grouped under the following warning:

WARNING: The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 98/79/EC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.