Medicinsk udstyr – Kvalitetsledelsessystemer – Krav angående opfyldelse af lovmæssige formål

Medical devices – Quality management systems – Requirements for regulatory purposes

DANSK STANDARD
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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ICS 03.100.70; 11.040.01

English Version

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 28 March 2018 for incorporation in the official English version of the EN.

Ce corrigendum prendra effet le 28 Mars 2018 pour incorporation dans la version anglaise officielle de la EN.

Die Berichtigung tritt am 28.März 2018 zur Einarbeitung in die offizielle Englische Fassung der EN in Kraft.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 13485:2016/AC:2018: E

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1 Modification to the European foreword

Replace the current fourth paragraph

"This document supersedes EN ISO 13485:2012."

with the following:

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

2 Modification to the heading of Annex ZA

Replace the current heading of Annex ZAwith:

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

3 Modifications to ZA.0

Replace the 1st paragraphwith the following:

"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."

Delete the 3rd paragraph starting with "EN ISO 13485:2016 provides requirements...".

In NOTE 1, 1st sentence, replace the reference to the Directive with "Directive 90/385/EEC" *to read*:

"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."

Delete the last sentence in NOTE 2 to read:

"NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 4, 5, 8, 9 and 10 of the Directive."

4 Modifications to ZA.1

In Table ZA.1, 12th row relating to 3.2, 3rd paragraph (b), replace in the 2nd column "5.1.1" *with* "5.1" *to read*:

"

3.2, 3rd paragraph (b)	4.2.2, 5.1	Covered.

"

In Table ZA.1, 15th row relating to 3.2 3rd paragraph (b) 3rd indent, replace in the 2nd column "8.5.1" *with* "8.2.2" *to read:*

"

3.2 3rd paragraph (b) 3rd indent	1, 4.1, 4.2, 7.4, 8.2.2	Covered.

"

In Table ZA.1, 23th row relating to 3.2, 3rd paragraph (e), delete in the 2nd column "7.5.1" *to read:*

"

3.2, 3rd paragraph (e)	4.2, 7.1, 7.4.3, 7.5.9.1, 7.6, 8.2.6	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.

"

In Table ZA.2, 13th row relating to 3.2, 3rd paragraph (b), 3rd indent, replace in the 2nd column "8.5.1" *with* "8.2.2" *to read:*

"

3.2, 3rd paragraph (b), 3rd indent	1, 4.1, 4.2, 7.4, 8.2.2	Covered.

"

In Table ZA.2, 15th row relating to 3.2, 3rd paragraph (c), 2nd indent, replace in the 2nd column "7.5.3" *with* "7.5.8, 7.5.9" *to read*:

"

3.2, 3rd paragraph (c), 2nd indent	4.2, 7.5.8, 7.5.9	Covered.

"

Last paragraph, replace the existing text of WARNING 1 and WARNING 2 with the following:

"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."

5 Modification to the heading of Annex ZB

Replace the current heading of Annex ZBwith:

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

6 Modifications to ZB.0

Replace the 1st paragraphwith the following:

"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."

Delete the 3rd paragraph starting with "EN ISO 13485:2016 provides requirements...".

Delete the last sentence in NOTE 2 to read:

"NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive."

7 Modifications to ZB.1

In Table ZB.1, 14th row relating to 3.2, 3rd paragraph (b), 2nd indent, replace in the 2nd column "8.2.2" *with* "8.2.4" *to read:*

"

3.2, 3rd paragraph (b), 2nd indent	4.1, 5.6, 7.1, 8.2.4, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.

"

In Table ZB.1, 15th row relating to 3.2, 3rd paragraph (b), 3rd indent, replace in the 2nd column "8.5.1" *with* "8.2.2" *to read:*

"

3.2, 3rd paragraph (b), 3rd indent	1, 4.1, 4.2, 7.4, 8.2.2	Covered.

"

In Table ZB.1, replace the 27th row relating to 3.2, 3rd paragraph (d) with:

"

3.2, 3rd paragraph (d)	4.2, 7.1, 7.5, 7.6, 8.1, 8.2.5, 8.2.6	Covered.

"

In Table ZB.1, 32th row relating to 3.2, 3rd paragraph (e), delete in the 2nd column "7.5.1" *and replace* "8.2.4" *with* "8.2.6" *to read:*

"

3.2, 3rd paragraph (e)	4.2, 7.1, 7.4.3, 7.5.9.1, 7.6, 8.2.6	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.

"

In Table ZB.2, 15th row relating to 3.2 3rd paragraph (b) 2nd indent, replace in the 2nd column "8.2.2" *with* "8.2.4" *to read:*

"

3.2 3rd paragraph (b) 2nd indent	4.1, 5.6, 7.1, 8.2.4, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.

"

In Table ZB.2, 16th row relating to 3.2 3rd paragraph (b) 3rd indent, replace in the 2nd column "8.5.1" *with* "8.2.2" *to read:*

"

3.2 3rd paragraph (b) 3rd indent	1, 4.1, 4.2, 7.4, 8.2.2	Covered.

"

In Table ZB.2, 18th row relating to 3.2 3rd paragraph (c) 2nd indent, replace in the 2nd column "7.5.3" *with* "7.5.8, 7.5.9" *to read:*

"

3.2 3rd paragraph (c) 2nd indent	4.2, 7.5.8, 7.5.9	Covered.

"

In Table ZB.2, last row relating to 3.2 3rd paragraph (d), replace in the 2nd column "8.2.4" *with* "8.2.6" *to read:*

"

3.2 3rd paragraph (d)	7.1, 7.4.3, 7.6, 8.2.6	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.

"

In Table ZB.3, 13th row relating to 3.2, 2nd paragraph, 2nd indent, replace in the 2nd column "8.2.4" *with* "8.2.6" *to read:*

"

3.2, 2nd paragraph, 2nd indent	7.1, 7.4.3, 7.6, 8.2.6	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.

"

In Table ZB.3, 14th row relating to 3.2, 2nd paragraph, 3rd indent, replace in the 2nd column "8.2.2" *with* "8.2.4" *to read:*

"

3.2, 2nd paragraph, 3rd indent	4.1, 5.6, 7.1, 8.2.4, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.

"

In Table ZB.3, 16th row relating to 3.2, 2nd paragraph, 5th indent, replace in the 2nd column "1" *with* "1.2" *and* "8.5.1" *with* "8.2.2" *to read*:

"

3.2, 2nd paragraph, 5th indent	1.2, 4.1, 4.2, 7.4, 8.2.2	Covered.

"

Last paragraph, replace the existing text of WARNING 1 and WARNING 2 with the following:

"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."

8 Modification to the heading of Annex ZC

Replace the current heading of Annex ZC with:

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

9 Modifications to ZC.0

Replace the 1st paragraphwith the following:

"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."

Delete the 3rd paragraph starting with "EN ISO 13485:2016 provides requirements...".

Delete the last sentence in NOTE 2 to read: "The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive."

10 Modifications to ZC.1

In Table ZC.1, 2nd row relating to 3, 1st indent, replace in the 2nd column "4.2.3" *with* "4.2.1.2" *to read*:

"

3, 1st indent	4.2.1.2, 7.2, 7.3.2, 7.3.3, 7.3.10	Covered provided that the documentation containing a general description of the medical device includes any variants.

"

In Table ZC.1, 5th row relating to 3, 4th indent, add "4.1, 4.2" *in the 2nd column to read*:

"

3, 4th indent	4.1, 4.2	Covered provided that, in the case of devices containing tissues of human origin or substances derived from such tissue, the quality management system documentation includes information on the origin of such material and on the conditions in which it was collected,

"

In Table ZC.1, 8th row relating to 3, 7th indent, replace in the 2nd column "7.5.1.2, 7.5.1.3, 7.5.2" with "7.5.2, 7.5.5, 7.5.7" *to read*:

"

3, 7th indent	6.4, 7.5.2, 7.5.5, 7.5.7	Covered.

"

In Table ZC.1, 9th row relating to 3, 8th indent, replace in the 2nd column "7.5.1, 7.5.9.1" *with* "7.1.8.1" *and* "8.2.3, 8.2.4" *with* "8.2.5, 8.2.6" *to read*:

"

3, 8th indent	4.2.1, 7.1.8.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.5, 8.2.6	Covered.

"

In Table ZC.1, 11th row relating to 3, 10th indent, replace in the 2nd column "4.2.4, 8.2.4" *with* "4.2.5, 8.2.6" *to read:*

"

3, 10th indent	4.2.5, 8.2.6	Covered.

"

In Table ZC.1, 12th row relating to 3, 11th indent, 2nd column, add "4.1, 4.2" *to read:*

"

3, 11th indent	4.1, 4.2	Covered provided that the quality management system documentation includes data from studies in a clinical or other appropriate environment or result from relevant bibliographical references showing adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used.

"

In Table ZC.1, 13th row relating to 3, 12th indent, replace in the 2nd column "4.2.3" *with* "4.2.1.2" *to read*:

"

3, 12th indent	4.2.1.2	Covered providing the quality management system documentation includes the labels and instructions for use.

"

In Table ZC.1, 16th row relating to 4, paragraph 2, 1st indent, replace in the 2nd column "1" *with* "1.2" *to read*:

"

4, paragraph 2, 1st indent	1.2, 4.2.2, 5.1, 5.5.1, 5.5.2	Covered.

"

In Table ZC.2, 14th row relating to 3.2, 2nd paragraph (b), 2nd indent, replace in the 2nd column "8.2.2" *with* "8.2.4" *to read:*

"

3.2, 2nd paragraph (b), 2nd indent	5.6, 8.2.4, 8.3, 8.5.2	Covered.

"

In Table ZC.2, 20th row relating to 3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 7th indent, replace in the 2nd column "7.5.1.2, 7.5.2, 7.5.6" *with* "7.5.2, 7.5.5, 7.5.7" *to read:*

"

3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 7th indent	6.4, 7.5.2, 7.5.5, 7.5.7	Covered.

"

In Table ZC.2, 21th row relating to 3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 8th indent, replace in the 2nd column "8.2.3, 8.2.4" *with* "8.2.5, 8.2.6" *to read*:

"

3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 8th indent	4.2.1, 7.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.5, 8.2.6	Covered.

"

In Table ZC.2, 23th row relating to 3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 10th indent, replace in the 2nd column "4.2.4, 8.2.4" *with* "4.2.5, 8.2.6" *to read:*

"

3.2, 2nd paragraph (c), 2nd indent reference to Annex III – section 3 10th indent	4.2.5, 8.2.6	Covered.

"

In Table ZC.2, last row relating to 3.2, 2nd paragraph (e), replace in the 2nd column "8.2.4" *with* "8.2.6" *to read:*

"

3.2, 2nd paragraph (e)	7.1, 7.4.3, 7.6, 8.2.6	Covered provided that the documented frequency at which tests are carried out is detailed in the quality management system documentation.

"

In Table ZC.3, 16th row relating to 3.2, 3rd paragraph (b), 2nd indent, replace in the 2nd column "8.2.2" *with* "8.2.4" *to read:*

"

3.2, 3rd paragraph (b), 2nd indent	5.6, 8.2.4, 8.3, 8.5.2	Covered.

"

In Table ZC.3, last row relating to 3.2, 3rd paragraph (d), replace in the 2nd column "7.6, 8.2.4" *with* "7.4.3, 7.6, 8.2.6" *to read*:

"

3.2, 3rd paragraph (d)	4.2, 7.1, 7.4.3, 7.6, 8.2.6	Covered provided that the frequency at which tests are carried out is documented in the quality management system documentation.

"

Last paragraph, replace the existing text of WARNING 1 and WARNING 2 with the following:

"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."