INTERNATIONAL STANDARD

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AMENDMENT 1
2014-07-15

Packaging for terminally sterilized medical devices —

Part 2:
Validation requirements for forming, sealing and assembly processes

AMENDMENT 1

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

AMENDEMENT 1

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Foreword

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The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

ISO 11607 consists of the following parts, under the general title Packaging for terminally sterilized medical devices:

— *Part 1: Requirements for materials, sterile barrier systems and packaging systems*

— *Part 2: Validation requirements for forming, sealing and assembly processes*

Packaging for terminally sterilized medical devices —

Part 2: Validation requirements for forming, sealing and assembly processes

AMENDMENT 1

Page 2, definition 3.9

Update the date of publication of the reference to read '[ISO 9000:2005]'.

Page 4, 4.1.2

Replace 'It is not necessary' with 'It shall not be necessary'.

Page 4, 4.1.3

Replace 'Health care facilities may use' with 'Health care facilities shall consider using'.

Page 7, 5.3.2 b), Note

Replace 'See EN 868-5: 1999, 4.3.2' with 'See EN 868-5: 2009, 4.3.2'

Page 11, Bibliography

Replace reference [2] with ISO 2859-1:1999 (including Corrigendum 1:2001 + Amendment 1:2011), *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

Replace reference [3] with ISO 9001:2008 (including Corrigendum 1:2009), *Quality management systems — Requirements*

Replace reference [5] with ISO 13485:2003 (including Corrigendum 1:2009), Medical devices — Quality management systems — Requirements for regulatory purposes

Replace reference [6] with ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

Replace reference [7] with EN 868-5:2009, *Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods*

Replace reference [8] with EN 868-6:2009, *Packaging for terminally sterilized medical devices — Part 6: Paper for low temperature sterilization processes — Requirements and test methods*

Replace reference [9] with EN 868-8:2009, *Packaging for terminally sterilized medical devices — Part 8: Re-usable sterilization containers for steam sterilizers conforming to* EN 285 — *Requirements and test methods*

Replace reference [10] with EN 13795-1+A1:2009, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 1: General requirements for manufacturers, processors and products*

Delete reference [11].

Replace reference [12] with AAMI/ANSI ST 65:2008, *Processing of reusable surgical textiles for use in health care facilities*

Replace reference [13] with DIN 58953-7:2010, *Sterilization — Sterile supply — Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels*

Replace reference [14] with DIN 58953-8:2010, *Sterilization — Sterile supply — Part 8: Logistics of sterile medical devices*

Replace reference [15] with DIN 58953-9:2010, *Sterilization — Sterile supply — Part 9: Use of sterilization container*

Renumber the Bibliography.

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