Packaging for terminally sterilized medical devices —
Part 2: Validation requirements for forming, sealing and assembly processes

AMENDMENT 1

En ballages des dispositifs médicaux stérilisés au stade terminal —
Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

AMENDEMENT 1
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 [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


Renumber the Bibliography.