

INTERNATIONAL
STANDARD

ISO
11607-2

First edition
2006-04-15

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

STANDARDSISO.COM : Click to view full PDF of ISO 11607-2:2006/Amd.1:2014



Reference number
ISO 11607-2:2006/Amd.1:2014(E)

© ISO 2014



COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

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*

STANDARDSISO.COM : Click to view the full PDF of ISO 11607-2:2006/Amd 1:2014

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]'.
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

Page 4, 4.1.2

Replace 'It is not necessary' with 'It shall not be necessary'.
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

Page 4, 4.1.3

Replace 'Health care facilities may use' with 'Health care facilities shall consider using'.
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

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'
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

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*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

Replace reference [3] with ISO 9001:2008 (including Corrigendum 1:2009), *Quality management systems — Requirements*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

Replace reference [5] with ISO 13485:2003 (including Corrigendum 1:2009), *Medical devices — Quality management systems — Requirements for regulatory purposes*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

Replace reference [6] with ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

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*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

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*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

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*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

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*
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

Delete reference [11].
STANDARDSCSC.COM: Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014

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.

STANDARDSISO.COM : Click to view the full PDF of ISO 11607-2:2006/Amd.1:2014