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**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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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

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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*