
**Packaging for terminally sterilized
medical devices —**

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

Emballages des dispositifs médicaux stérilisés au stade terminal —

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



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Foreword

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ISO 11607-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11607-1 and ISO 11607-2 cancel and replace ISO 11607:2003, which has been technically revised.

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*