



ISO 11607-3

Packaging for terminally sterilized medical devices —

Part 3: Requirements for process development for forming, sealing and assembly

*Emballages des dispositifs médicaux stérilisés au stade
terminal —*

*Partie 3: Exigences relatives à la mise au point des procédés de
formage, scellage et assemblage*

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ISO 11607-1 and ISO 11607-2 specify requirements for the design and validation of sterile barrier systems for terminally sterilized medical devices, and the validation requirements for manufacturing processes of sterile barrier systems, respectively. The heat sealing of a sterile barrier system is critical to the maintenance of sterile barrier integrity to the point of use; however, there is little content available for process development in the current edition of ISO 11607-2.

This document specifies requirements for the development of heat sealing processes to meet sterile barrier seal design requirements. A thorough development process with a high-quality output is an important input to an efficient validation of the process. While a successful validation is essential to ensure the safety of terminally sterilized medical devices, there is no intention to imply that the process development approach proposed in this document is the only valid approach. Users of this document can use the activities described in this document to control risks associated with heat sealing processes, if they find it appropriate. Additionally, this document specifies a process for documenting the equivalence of heat sealing processes which can be a benefit to users in support of change control activities since it can create the basis to leverage the efforts over a range of heat sealing equipment or over a sterile barrier system family.

This document is intended for use by industrial manufacturers engaged in the design and development of sterile barrier systems and heat sealing processes. Effective application of the requirements described in this document requires proficiency in design of experiment (DOE) methodologies and access to the requisite testing resources for result evaluation. Producers of preformed sterile barrier systems, as well as medical device manufacturers, rely heavily on heat sealing, among other techniques, to create sterile barrier systems that ensure device integrity and sterility at various stages of distribution and handling of sterile devices until the point of use and aseptic presentation. This process often involves the operation of multiple, interchangeable heat sealers to produce commercial quantities of sterile barrier systems.

For healthcare facilities (e.g. hospitals), ISO/TS 16775:2021, Annex B contains all relevant guidance for sterile barrier system closure technologies including sealing, reusable container closures and wrapping processes.