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Second edition  
2019-02

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## **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*



Reference number  
ISO 11607-2:2019(E)

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## 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](http://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](http://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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11607-2:2006), which has been technically revised. It also incorporates the amendment ISO 11607-2:2006/Amd.1:2014.

The main changes compared to the previous edition are as follows:

- terms and definitions for “process variable”, “process parameter” and “monitoring of processes” have been added;
- various definitions have been aligned with the latest version of ISO 11139;
- the terminology of “critical” process parameters has been discontinued and the concept of a process specification has been introduced to include all elements required to manufacture a product that consistently meets specifications.

A list of all parts in the ISO 11607 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

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## Introduction

Packaging for terminally sterilized medical devices should be designed and manufactured to ensure that the medical device can be sterilized and remain sterile under documented storage and transport conditions until the sterile barrier system is damaged or opened.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. Medical devices delivered in a sterile state should have been manufactured, packed and sterilized by appropriate, validated methods. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

There should be a documented process validation programme demonstrating the efficacy and reproducibility of all packaging and sterilization processes. Along with the sterilization process, some of the packaging operations that can affect sterile barrier system integrity are sealing, capping or other closure systems, cutting, form/fill/seal, assembly processes and subsequent handling. This document provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. Guidance for ISO 11607 series can be found in ISO/TS 16775.

The term “sterile barrier system” was introduced in 2006 to describe the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header bags or hospital packaging reels.

The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device. Preformed sterile barrier systems sold to health care facilities for use in internal sterilization are considered medical devices in many parts of the world.