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BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

टर्मिनली स्टरलाइज़्ड चिकित्सा उपकरणों के लिए पैकेजिंग - आईएसओ 11607-1 और आईएसओ 11607-2 के अनुप्रयोग पर मार्गदर्शन

Draft Indian Standard

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

[ICS 11.080.30]

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	Last date for comments: **20 Nov 2023**

NATIONAL FOREWORD
(*Adoption clause will be added later*)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	IS/ISO 11607 : 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems First Revision	Identical

ISO 11607-2:2019, Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	IS/ISO 11607 : 2019 Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision)	Identical

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (Second Revision)'.

In reporting the result of a test or analysis made in accordance with this standard, is to be rounded off, it shall be done in accordance with IS 2 : 2022 'Rules for rounding off numerical values (Second Revision)'.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO/TS 16775:2021 or kindly contact:

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Scope

This document provides guidance for the application of the requirements contained in ISO 11607-1 and ISO 11607-2. It does not add to, or otherwise change, the requirements of ISO 11607-1 and ISO 11607-2. This is an informative document, not normative. It does not include requirements to be used as basis of regulatory inspection or certification assessment activities.

The guidance can be used to better understand the requirements of ISO 11607-1 and ISO 11607-2 and illustrates the variety of methods and approaches available for meeting the requirements of those International Standards. It is not required that this document be used to demonstrate conformity with them.

Guidance is given for evaluation, selection and use of packaging materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Guidance on validation requirements for forming, sealing and assembly processes is also given.

This document provides information for both healthcare facilities and the medical devices industry for terminally sterilized medical devices.

This document does not provide guidance for applications of packaging materials and systems after their opening. In the use of packaging for other purposes such as a "sterile field" or transport of contaminated items, other regulatory standards will apply.