Technical Information Report

AAMI/ISO TIR16775: 2014

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

AAMI
Advancing Safety in Healthcare Technology

A Technical Report prepared by AAMI and registered with ANSI

AAMI/ISO TIR16775:2014
(Revision of AAMI TIR22:2007)

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

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Association for the Advancement of Medical Instrumentation

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American National Standards Institute

Abstract: This technical report contains guidance on the application of ISO 11607-1:2006, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ISO 11607-2:2006, *Packaging for terminally sterilized medical device - Part 2: Validation requirements for forming, sealing, and assembly processes*. Possible options for compliance with the requirements of Parts 1 and 2 will be addressed as special concerns that may require attention due to regional or local conditions, practices or regulations.

Keywords: sterile barrier systems, packaging systems, terminally sterilized

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI/ST/WG 07, Packaging Working Group

The adoption of ISO/TS 16775:2014 as a Technical Report and revision of existing AAMI TIR22:2007 was initiated by the AAMI Packaging Working Group, which serves as the U.S. TAG (technical advisory group) for ISO/TC 198/WG 7. U.S. representatives played an active role in developing the ISO TR.

Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, **the AAMI Packaging Working Group** had the following members:

Chairs:
David W. Johnson, Kimberly-Clark Corporation
Jackie Daly Johnson, Flexible Packing Association

Members:
Edward Arscott, NAMSA
Donald S. Barcan, DBI Inc (Donbar Industries Inc)
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Abigail Walton, CareFusion

NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO/TS 16775:2014

International Technical Specification ISO/TS 16775 was developed by Working Group (WG) 7, *Packaging*, of Technical Committee (TC) 198, *Sterilization of health care products* of the International Organization for Standardization (ISO).

U.S. participation in ISO/TC 198/WG 7 is organized through the U.S. Technical Advisory Group (TAG) for ISO/TC 198, administered by AAMI on behalf of the American National Standards Institute (ANSI).

This edition replaces and revises AAMI TIR22:2007.

AAMI encourages its committees to harmonize their work with international documents as much as possible. The AAMI Packaging Working Group reviewed ISO/TS 16775 to formulate the U.S. position while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. As the U.S. Technical Advisory Group for ISO/TC 198/WG 7, the AAMI Packaging Working Group voted to adopt the ISO Technical Specification as written.

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the document. "Should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the report. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

The concepts incorporated into this technical report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new date comes to light.

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Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington VA 22203-1633.

NOTE—Beginning with the ISO foreword on page x, AAMI/ISO TIR16775:2014, *Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2* is identical to ISO/TS 16775:2014.
