Recognized Consensus Standards

Part B: Supplementary Information Sheet (SIS)
FR Recognition List Number 038 **Date of Recognition** 01/27/2015
FR Recognition Number 14-456
Standard

ISO /TS 16775 First edition 2014-05-15
Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2

U.S. Identical Adoption

ANSI AAMI ISO TIR16775:2014
Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2

Scope/Abstract

ISO/TS 16775:2014 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/or ISO 11607 2. It is an informative document, not normative, and 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/or ISO 11607 2 and illustrates some of the variety of methods and approaches available for meeting the requirements of those International Standards. It is not required to be used to demonstrate compliance with them.

Guidelines are 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.

Extent of Recognition

Complete standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

Relevant FDA Guidance and/or Supportive Publications

ISO 11607-1 First edition 2006-04-15, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, **sterile** barrier systems and packaging systems processes [Including: Amendment 1 (2014)]

ISO 11607-2 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)] (Sterility)

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Standards Development Organization

ISO International Organization for Standardization https://www.iso.org/[22]

FDA Specialty Task Group (STG)

Sterility

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