



PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES

ANSI/AAMI/ISO 11607:2006

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With the newly released revision of ANSI/AAMI/ISO 11607:2006, Packaging for terminally sterilized medical devices, you may find yourself wondering how the document has changed and what it means to the industry.

Nelson Laboratories, Inc. (NLI) had several members on the ISO Technical Committee Work Group 7 who were involved in the revision of this standard. This publication represents a harmonized version of the former ISO 11607 and EN868-1. This standard has been developed to meet the European Requirements of the European Medical Device Directive and is expected to become an FDA consensus standard sometime this fall. With the acceptance of the FDA consensus standard, manufacturers can use one validation to fulfill both regulatory body requirements.

The first thing that warrants attention is the fact that the document has been split into two parts. Before a package for a terminally sterilized medical device can be designed, it is necessary to evaluate all the characteristics and requirements of the device which could affect the design of the package. The first part of the standard addresses the basic attributes required of materials and preformed systems while considering a wide range of materials, sterilization, medical devices, and packaging system designs. One of the annexes in part one, provides an extensive centralized list of recommended test methods to evaluate these attributes.

The second part of the standard, which is a completely new addition, is geared towards process development and validation. It addresses items such as test methods, installation, operational, and performance qualification methods. This is a critical issue that ensures the integrity of the packaged device is attained and will remain so until opened by the user. A major hurdle in creating this global standard was agreeing on terminology. Four new definitions were generated to assist in making the document more clear and consistent:

Sterile Barrier System (SBS) – “Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use”

Preformed Sterile Barrier System – “Sterile barrier system that is supplied partially assembled for filling and final closure”

Protective Packaging – “Configuration of materials designed to prevent damage to the sterile barrier system and its contents from their time of assembly to the point of use”

Packaging System – “Combination of the sterile barrier system and protective packaging”



In addition to the release of this standard, TIR22:2007 has recently undergone revision with the objective of providing guidance on the applications of the new 11607 document.

It is crucial to assure package integrity for sterile medical devices. The methods developed at NLI conform to the standard covered in ISO 11607 "Packaging for terminally sterilized medical devices". Some of the NLI validated package tests available to help meet the requirements of ISO 11607 consist of:

Microbial barrier - we offer two options on this area, a whole package microbial aerosol challenge test and the ASTM F1608 Microbial Ranking (Exposure Chamber Method). The whole package test includes the microbial challenge, subsequent sterility testing on the packaged product to determine penetration of the indicator organism used and test controls. The ASTM F1608 is specific to porous materials and employs a low flow rate, extended exposure time, and increased challenge level, which allows testing of materials with high differential pressure values.

Dye migration - The package is examined for evidence of seal failure demonstrated by dye slipping through the seal.

Bubble emission - A probe is inserted into the samples package and the machine started. The package is submerged in an immersion fluid.

Burst/Creep test - The burst test determines package strength by pressurizing a package until it bursts. The creep test determines package strength by pressurizing a package at 80% of the known burst pressure for a set amount of time.

Seal Peel - The sample segment is inserted into the grips of an instrument with the heat seal centered between the two grips. The results are reported as maximum load.

Accelerated aging - Simulated aging studies can be run with a designated time period ranging from one month to five years (or longer). The time of simulated aging depends on the temperature at which the products are held. Real-time aging is required when establishing an expiration date. Accelerated aging is an option allowing manufacturers the ability to get product to market faster.

NLI has been performing package testing for many years and has a dedicated section to assist with compliance to ISO 11607. To find out more regarding packaging testing, please visit our web site <http://www.nelsonlabs.com/medical-device/packagin.jsp> or contact Wendy Mach at wmach@nelsonlabs.com. Contact the Nelson Sales team for a quote and our complete list of packaging test services at sales@nelsonlabs.com.