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(ICS 11.080.30)

SINGAPORE STANDARD

Standard guide for accelerated aging of sterile barrier systems for medical devices

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Standard guide for accelerated aging of sterile barrier systems for medical devices

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The content of this Singapore Standard was approved on 30 August 2019 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

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BHSC sets up the Technical Committee on Quality Management Systems to oversee the preparation of this standard. The Technical Committee consists of the following members:

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The Technical Committee sets up the National Mirror Working Group on ISO/TC 210 to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

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The organisations in which the experts of the National Mirror Working Group are involved are:

Access-2-Healthcare
BioPharmaSpec UK Ltd
Edwards Lifesciences (Singapore) Pte Ltd
Sanmina Corporation Singapore
Singapore Manufacturing Federation (Medical Technology Industry Group)
Stendard
SysteMED Pte Ltd
TÜV SÜD PSB Pte Ltd
Wise Consultants and Services Pte Ltd

Contents

Foreword

This Singapore Standard was prepared by the National Mirror Working Group on ISO/TC 210 set up by the Technical Committee on Quality Management Systems under the purview of BHSC.

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NOTE – Reference to International Standards are replaced by applicable Singapore Standards / Technical References.

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Standard guide for accelerated aging of sterile barrier systems for medical devices

1. Scope

1.1 This guide provides information for developing accelerated aging protocols to rapidly determine the effects, if any, due to the passage of time on the sterile integrity of the sterile barrier system (SBS), as defined in ANSI/AAMI/ISO 11607–1:2006 and the physical properties of their component packaging materials.

1.2 Information obtained using this guide may be used to support expiration date claims for medical device sterile barrier systems.

1.3 The accelerated aging guideline addresses the sterile barrier systems in whole with or without devices. The sterile barrier system material and device interaction compatibility that may be required for new product development or the resulting evaluation is not addressed in this guide.

1.4 Real-time aging protocols are not addressed in this guide; however, it is essential that real-time aging studies be performed to confirm the accelerated aging test results using the same methods of evaluation.

1.5 Methods used for sterile barrier system validation, which include the machine process, the effects of the sterilisation process, environmental challenge, distribution, handling, and shipping events, are beyond the scope of this guide.

1.6 This guide does not address environmental challenging that stimulates extreme climactic conditions that may exist in the shipping and handling environment. Refer to Practice D4332 for standard conditions that may be used to challenge the sterile barrier system to realistic extremes in temperature and humidity conditions. See Terminology F1327 for a definition of "environmental challenging."

1.7 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2 Referenced documents

2.1 *ASTM Standards:*[1]

D4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing

E337 Test Method for Measuring Humidity with a Psychrometer (the Measurement of Wet- and Dry-Bulb Temperatures)

F17 Terminology Relating to Flexible Barrier Packaging

F1327 Terminology Relating to Barrier Materials for Medical Packaging (Withdrawn 2007)

F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

[1] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

2.2 *AAMI Standards:*

ANSI/AAMI/ISO 11607–1: 2006, Packaging for Terminally Sterilized Medical Devices[2]

AAMI TIR 22–2007, Guidance for ANSI/AAMI/ISO 11607, Packaging for Terminally Sterilized Medical Devices[2]