

American National Standard



ANSI/AAMI/ ISO 11737-2: 2019

Sterilization of medical
devices—Microbiological
methods—Part 2: Tests
of sterility performed in
the definition, validation
and maintenance of a
sterilization process

Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

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Abstract: Specifies the general criteria for tests of sterility on medical devices that have been exposed to a treatment with the sterilizing agent that is a fraction of the specified sterilization process. These tests are intended to be performed when defining, validating or maintaining a sterilization process.

Keywords: health care products, medical equipment, sterilization, tests, validation, packages, 11737-2

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Committee representation

Association for the Advancement of Medical Instrumentation

Microbiological Methods Working Group

The adoption of ISO 11737-2 as an American National Standard was initiated by the AAMI Microbiological Methods Working Group. AAMI ST/WG 8 provides input to the AAMI Sterilization Standards Committee which is the responsible group for providing the U.S. input to the relevant group in ISO/TC 198. U.S. representatives from AAMI Microbiological Methods Working Group and the TAG played an active part in developing the ISO document.

At the time this document was published, the **AAMI Microbiological Methods Working Group** has the following members:

Cochairs: Carolyn Braithwaite-Nelson
Amy Karren

Members: Anas Aljabo, CMC Sterilization Ltd
Christopher Anderson, Johnson & Johnson
Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC
Erika Bawor, Insulet Corporation
Jennifer Berg, Sterilucent Inc
Michael Brady, Toxikon Corporation
Carolyn Braithwaite-Nelson, Philips
Trabue Bryans, BryKor LLC
Linnette Cachares, Arthrex Inc
Robb Calabro, AbbVie
Glenn Calvert, Tech Group North America dba West
Sarah Chamberlain, Avista Pharma Solutions Inc
Christina Cloutier, Case Medical Inc
Sean Colwell, WuXi AppTec Inc
Lisa Cook, B Braun of America Inc
Gary Cranston, Consulting & Technical Services/PCS
Emily Craven, Mevex Corporation
Elaine Daniell, EDan-SA LLC
Douglas Davie, Sterilization Validation Services
Michael Douthit, BSI Healthcare
Mary Ann Drosnock, Healthmark Industries Company Inc
Gordon Ely, GEM Consulting
Plamena Entcheva-Dimitrov, Preferred Regulatory Consulting Inc
Niki Fidopiastis, NAMSA
Dan Floyd, DuPont Tyvek Medical and Pharmaceutical Protection
Scott Giraud, Medtronic Inc Campus
Elizabeth Gonzalez, FDA/CDRH
Chris Haas, Getinge USA
Douglas Harbrecht, Sterility Assurance LLC
Deborah Havlik, Hospira, a Pfizer company
Beth Jacques, STERIS Corporation
Nupur Jain, Intuitive Surgical Inc
Amy Karren, WL Gore & Associates
Christine Loshbaugh, Edwards Lifesciences
Jo-Ann Maltais, Maltais Consulting
Jeffrey Martin, Sterilization and Quality System Consulting LLC
Tom McElroy, IUVO BioScience

David McGoldrick, Abbott Laboratories
 Nicole McLees, 3M Healthcare
 Russell Mills, GE Healthcare
 Vanessa Molloy-Simard, TSO3 Inc
 Peter Noverini, Baxter Healthcare Corporation
 Gerry O'Dell, Gerry O'Dell Consulting
 Jonathan Olson, Cantel Inc
 David Opie, Noxilizer Inc
 Dave Parente, Ecolab
 Kimberly Patton, Becton Dickinson & Company
 Lori Patzner, Cook Inc
 Antonio Prado, Cardinal Health
 Marcus Reese, Terumo BCT
 Keith Reiner, Terumo Americas Corporate
 Beau Rollins, ConvaTec Inc QARAC Global Headquarters
 Tyrone Rouse, Owens & Minor
 Manuel Saavedra, Avanos Medical
 Anita Sawyer
 Michael Schoene, Bausch & Lomb Inc
 Harry Shaffer, Sterilization Consulting Services
 Arnold Shechtman, Validation Challenges Consulting LLC
 Mary Sheehan, BSI Healthcare
 Kristen Spigiel, Stryker Instruments Division
 Michael Sprague, Ethide Laboratories
 Laxmishita Sreedasyam, Boston Scientific Corporation
 Sopheak Srun, Quality Tech Services LLC
 Radhakrishna Tirumalai, US Pharmacopeia Convention Inc
 Donald Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
 Richard Weisman, Fresenius Medical Care
 Beverly Whitaker, Indigo Consulting Group LLC
 Martell Winters, Sotera Health LLC

Alternates: Tess-Simone Brill, WL Gore & Associates Inc
 David Brodersen, Getinge USA
 David Brodersen, LexaMed Ltd
 Bradley Catalone, TSO3 Inc
 Nicole Cufaude, Medtronic Inc Campus
 Darren Dahlin, Cantel Inc
 Bethany Daniell, EDan-SA LLC
 Kimbrell Darnell, Becton Dickinson & Company
 Zachary Dukerich, Arthrex Inc
 Robert Grizzle, BSI Healthcare
 Trang Hoang, Edwards Lifesciences
 Nichole Jackson, Ecolab
 Wade Johnston, Avanos Medical
 Peter Kalkbrenner, Sterilucent Inc
 Jacob Killian, IUVO BioScience
 Satu King, Philips
 Carolyn Kinsley, LexaMed Ltd
 Dan Klein, STERIS Corporation
 Mark Krocko, Mevex Corporation
 Kaumudi Kulkarni, Healthmark Industries Company Inc
 Michelle Luebke, Baxter Healthcare Corporation
 Patrick McCormick, Bausch & Lomb Inc

Koyejo Obadina, Abbott Laboratories
Karen O'Donovan, Boston Scientific Corporation
Alberto Paret, Cardinal Health
Nicole Pasquino, Case Medical Inc
Michelle Pierce, NAMSA
Aimee Ravgiala, Terumo BCT
Rafael Rodriguez, GE Healthcare
Michael Scholla, DuPont Tyvek Medical and Pharmaceutical Protection
Angel Soler-Garcia, FDA/CDRH
Molly Swanson, Quality Tech Services LLC
Leslie Tavares, WuXi AppTec Inc
Brian Wallace, Intuitive Surgical Inc
Scott Weiss, Johnson & Johnson
Carole White, Terumo Americas Corporate
Kristy Yates, 3M Healthcare

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

Background of ANSI/AAMI adoption of ISO 11737-2:2019

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO/TC 198 to fill a need for guidance regarding tests of sterility to be performed when defining, validating or maintaining a sterilization process.

U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group, AAMI/ST and AAMI ST/WG 8, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of sterilization. Upon review of ISO 11737-2, AAMI/ST and the AAMI ST/WG 8 decided to adopt it verbatim, as a third edition of ANSI/AAMI/ISO 11737-2:2019.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “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 standard. “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.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, 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 data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the ISO foreword on page viii, this American National Standard is identical to ISO 11737-2:2019.
