Designation: F2475 – 20

# Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials[1]

This standard is issued under the fixed designation F2475; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide provides information to determine the appropriate testing for biocompatibility of medical device packaging materials that have the potential to contact the patient directly or indirectly.

1.2 This guide does not apply to secondary or tertiary packaging materials.

1.3 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

F17 Terminology Relating to Primary Barrier Packaging

2.2 *Other Standards:*

ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process[3]

ANSI/AAMI/ISO 11607-1:2006(R2010) Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems[4]

FDA Center for Devices and Radiological Health: 2016 Biocompatibility Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (June 16, 2016)

## 3. Terminology

3.1 *Definitions*—For terminology related to barrier materials for medical packaging see Terminology F17.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *extent of contact*—degree to which the packaged device will contact the patient (refer to ISO 10993-1). When referring to the packaging, extent of contact refers to the degree to which the packaging will interact with the device. Degree of packaging contact (interaction) is related to the physical-chemical nature of the packaging materials and the device, the intended use of the device (which relates to the categorization of contact with the body), and the extent to which the packaging may negatively impact the contained device.

3.2.2 *packaging biocompatibility*—inherent ability of a material to protect against a chemical change in the packaged medical device that could result in an adverse response to the host in its intended application.

3.2.3 *packaging biocompatibility testing*—series of chemical and biological tests that a material is subjected to in order to determine the ability of the packaging material to protect against a chemical change in the packaged medical device that could result in an adverse response to the host in its intended application.

3.2.4 *sterile barrier system*—minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

## 4. Summary of Practice

4.1 Materials used in packaging are to be evaluated per defined guidelines, such as AAMI/ANSI/ISO 11607. The effect

[1] This guide is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.15 on Chemical/Safety Properties.

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[2] 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.

[3] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.