



Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices¹

This standard is issued under the fixed designation F3127; 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 considerations for validating cleaning processes for medical devices during initial fabrication and assembly prior to initial use. Validated cleaning processes are important for achieving consistency in function and consistency in biocompatibility. The considerations include but are not limited to, validation approach, equipment design, procedures and documentation, analytical methods, sampling, development of limits, and other issues.

1.2 Inclusions:

1.2.1 This guide describes the validation of critical cleaning processes for medical devices to reduce contaminants to acceptable levels prior to packaging.

1.3 Exclusions:

1.3.1 Reusable medical devices.

1.3.1.1 Validation of cleaning operations for reusable medical devices is not within the scope of this standard guide. Although cleaning of reusable medical devices is beyond the scope of this guide, many of the principles outlined in this guide may be applicable to the validation of cleaning operations for reusable devices.

1.3.2 Cleaning of medical devices in health care facilities.

1.3.2.1 Validation of cleaning processes in patient/health care facilities is not within the scope of this standard guide.

1.4 *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:²

¹ This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved April 1, 2016. Published May 2016. DOI: 10.1520/F3127-16

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.

D543 Practices for Evaluating the Resistance of Plastics to Chemical Reagents

E2857 Guide for Validating Analytical Methods

F619 Practice for Extraction of Medical Plastics

F2459 Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis

F2847 Practice for Reporting and Assessment of Residues on Single Use Implants

G121 Practice for Preparation of Contaminated Test Coupons for the Evaluation of Cleaning Agents

G122 Test Method for Evaluating the Effectiveness of Cleaning Agents

G131 Practice for Cleaning of Materials and Components by Ultrasonic Techniques

2.2 ANSI/AAMI/ISO Standards:³

ISO 10993-5 Biological Evaluation of Medical Devices—Part 5: Tests for Cytotoxicity, In Vitro Methods

ISO 10993-11 Biological Evaluation of Medical Devices—Art 11: Tests for Systemic Toxicity

ISO 10993-17 Biological Evaluation of Medical Devices—Part 17: Establishment of Allowable Limits for Leachable Substances

ISO 11737-1 Sterilization of Medical Devices—Microbiological Methods—Part 1: Determination of a Population of Microorganisms on Products

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices

AAMI ST72 Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing

AAMI TIR30 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices

2.3 United States Pharmacopoeia (USP) – General Chapters:

USP <85> Bacterial Endotoxins Test

USP <87> Biological Reactivity Tests, In Vitro

USP <88> Biological Reactivity Tests, In Vivo

USP <1225> Validation of Compendial Procedures

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.