Designation: D8179 – 18

Standard Guide for Characterizing Detergents for the Cleaning of Clinically-used Medical Devices[1]

This standard is issued under the fixed designation D8179; 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 Detergents play a critical role in the cleaning of clinically-used medical devices, but there are few consensus methods for describing the key characteristics of these detergents. This guide identifies consensus standards, ASTM and others, used to characterize detergents in other applications, which can also be used to characterize detergents used to clean clinically-used medical devices.

1.2 In identifying these test methods, manufacturers of detergents can reference this guide to characterize their detergents.

1.3 By identifying applicable test methods, gaps may be identified where development of new standardized test methods need to be developed to characterize detergents intended to clean medical devices.

1.4 By identifying applicable test methods that are used and results reported by detergent manufacturers, test results can be shared and may lead in the future to development of performance criteria for the key characteristics of detergent.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *Exclusions:*

1.6.1 This guide is not intended for detergents formulated to remove residues as a result of the manufacturing process.

1.6.2 This guide does not provide information related to disinfection or disinfecting agents that might be part of a detergent formulation.

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

1.8 *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]

D459 Terminology Relating to Soaps and Other Detergents

D471 Test Method for Rubber Property—Effect of Liquids

D543 Practices for Evaluating the Resistance of Plastics to Chemical Reagents

D820 Test Methods for Chemical Analysis of Soaps Containing Synthetic Detergents

D1172 Guide for pH of Aqueous Solutions of Soaps and Detergents

D2024 Test Method for Cloud Point of Nonionic Surfactants

D3048 Test Method of Assay for Alkaline Protease

D3519 Test Method for Foam in Aqueous Media (Blender Test) (Withdrawn 2013)[3]

D3601 Test Method for Foam In Aqueous Media (Bottle Test) (Withdrawn 2013)[3]

D7225 Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors

E2454 Guide for Sensory Evaluation Methods to Determine the Sensory Shelf Life of Consumer Products

F2809 Terminology Relating to Medical and Surgical Materials and Devices

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

F3208 Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices

F3293 Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices

G31 Guide for Laboratory Immersion Corrosion Testing of Metals

[1] This guide is under the jurisdiction of ASTM Committee D12 on Soaps and Other Detergents and is the direct responsibility of Subcommittee D12.15 on Physical Testing.

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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] The last approved version of this historical standard is referenced on www.astm.org.

G122 Test Method for Evaluating the Effectiveness of Cleaning Agents

2.2 *AAMI Documents:*[4]

AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

AAMI TIR34:2014 Water for the processing of medical devices

AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

2.3 *ISO Standards:*[5]

ISO 7827:2010 Water quality – Evaluation of the "ready", "ultimate" aerobic biodegradability of organic compounds in aqueous medium – Method by analysis of dissolved organic carbon (DOC)

ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-12:2009 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO/TS 15883-5:2005 Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy

2.4 *Other Documents:*

CSPA: DCC-15:2011 Cleaning Test Method DCC-15 Guidelines for Measuring Degree of Surface Abrasion[6]

EN 285:2015 Sterilization – Steam Sterilizers – Large Sterilizers[7]

EPA Test Guidelines for Pesticide Data Requirements "six pack tox testing"[8]

FDA Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling/Guidance for Industry and Food and Drug Administration Staff (Document updated on June 9, 2017)[9]

OECD 105:1995 Water Solubility[10]

OECD 301:1992 Test No 301: Ready Biodegradability[10]

OECD 310:2006 Test No. 310: Ready Biodegradability - CO_2 in sealed vessels (Headspace Test)[10]

3. Terminology

3.1 *Definitions:*

3.1.1 *cleaning , n*—removal of contamination from a medical device to the extent necessary for further processing of or for intended use.

3.1.2 *detergents, n*—a composition that removes soil. **D459**

3.1.3 *disinfection, n*—destruction or reduction of pathogenic and other kinds of microorganisms by thermal or chemical means.

3.1.4 *medical device, n*—any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: (1) diagnosis, prevention, monitoring, treatment, or alleviation of disease, (2) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury, (3) investigation, replacement, modification, or support of the anatomy or of a physiological process, (4) supporting or sustaining life, (5) control of conception, (6) disinfection of medical devices, and (7) providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means. **F2809**

3.1.5 *shelf-life, n*—the length of time recommended by the manufacturer, based upon testing, that a detergent may be fit for use after the date of manufacture.

4. Summary of Guide

4.1 *General Considerations*—This guide identifies ASTM and other consensus test methods to assess the characteristics of detergent cleaning agents intended for use when cleaning clinically used medical instruments and devices. Detergents are defined in 3.1.2 consistent with the ASTM D12 Terminology Guide. Detergents are made up of a system of cleaning agents with no one component solely responsible for its performance. Appropriate test methods may address components or the finished product, or both.

4.1.1 As a starting point this guide identifies useful test methods based on the list of characteristics for "ideal cleaning agents" identified in AAMI TIR 12 (Section 4.2.4.3, Cleaning Agents) and in AAMI ST79 (Section 7.6.3, Cleaning): non-abrasive; compatible with the medical device or container system to be cleaned as well as the materials used in the cleaning equipment itself; low-foaming; free-rinsing (that is, easily removed from the medical device); biodegradable; provides for soil dispersion or suspension; rapidly dissolve(s)/disperse(s) soil; is effective on clinically relevant soils under specified use conditions; is non-toxic in the specified use dilution; has a shelf life and use-life consistent with the anticipated clinical use; is cost-effective.

4.2 The following factors are a framework for identifying test methods that will be helpful to characterize detergent cleaning agents intended for use when cleaning clinically-used medical instruments and devices.

[4] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

[5] 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.

[6] Available from Household & Commercial Products Association, https://member.thehcpa.org.

[7] Available from European Committee for Standardization (CEN), Avenue Marnix 17, B-1000, Brussels, Belgium, http://www.cen.eu.

[8] Available from United States Environmental Protection Agency (EPA), William Jefferson Clinton Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460, http://www.epa.gov.

[9] Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, http://www.fda.gov.

[10] Available from the online library of the Organisation for Economic Cooperation and Development (OECD), www.oecd-ilibrary.org.