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.

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.

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