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Standard Guide for Blood Cleaning Efficiency of Detergents and Washer- Disinfectors¹

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1. Scope

1.1 This guide is based on a standardized test soil correlating to coagulated blood suitable for screening tests and the evaluation of the cleaning efficiency of washer-disinfectors used for reprocessing of surgical instruments. This guide strictly deals with cleaning and does not describe any methods that are related to disinfection. See the Referenced Documents D5343, D4008, D4265, D4488, D2960, D3050, in Section 2 for additional information.

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

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

2. Referenced Documents

2.1 ASTM Standards:²

D5343 Guide for Evaluating Cleaning Performance of Ceramic Tile Cleaners

D4008 Test Method for Measuring Anti-Soil Deposition Properties of Laundry Detergents (Not Suitable for Detergent Ranking)

D4265 Guide for Evaluating Stain Removal Performance in Home Laundering

D4488 Guide for Testing Cleaning Performance of Products Intended for Use on Resilient Flooring and Washable Walls (Withdrawn 2009)³

D2960 Guide for Controlled Laundering Test Using Naturally Soiled Fabrics and Household Appliances

D3050 Guide for Measuring Soil Removal from Artificially Soiled Fabrics (Not Suitable for Detergent Ranking)

2.2 AAMI Standards:⁴

ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AAMI TIR 12 Designing, testing, and labelling reusable medical devices for reprocessing in health care facilities: a guide for medical device manufacturers

ANSI/AAMI ST81 Sterilization of medical devices – information to be provided by the manufacturer for the processing of resterilizable medical devices

AAMI TIR 30 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

2.3 ISO Standards⁵

ISO 15883–2 Washer-disinfectors, part 2: requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

ISO/TS 15883–5:2005 Washer-disinfectors, part 5: test soils and methods for demonstrating cleaning efficacy of washer-disinfectors

3. Summary of Guide

3.1 The standardized test soil is based on a proteinous matrix containing fibrinogen and thrombin in two separated components. Coagulation and formation of fibrin fibers are induced after mixing the two components.

3.2 The suggested methods are based on the removal of standardized test soil as a result of mechanical or chemical action, or both, of the tested detergents or washer-disinfectors, or both. The screening test provides qualitative results for cleaning efficacy. After testing the practical situation in a washer-disinfectant, the end result is visually checked for immediate evaluation. Minor residue is detected by using the

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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.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁵ Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, <http://www.iso.org>.