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.

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Standard Guide for Assessment of Medical Gloves[1]

This standard is issued under the fixed designation D7103; 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 is intended to assist in the identification and application of the most appropriate ASTM and associated standards for the assessment, development of specifications, and selection of medical gloves with the ultimate goal of maintaining the safety and health of healthcare workers who may come into contact with biological and chemical hazards.

1.2 No guidance document or assessment protocol can ensure the selection of medical gloves that guarantees healthcare worker protection. The purpose of testing and assessing medical gloves is to generate the performance data and quality information that will allow the most appropriate assessment and selection of medical gloves. Ultimately, the selection of medical gloves shall be based on the evaluation of available technical data, quality information, and professional assessment of risk.

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]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

D3577 Specification for Rubber Surgical Gloves

D3578 Specification for Rubber Examination Gloves

D3767 Practice for Rubber—Measurement of Dimensions

D5151 Test Method for Detection of Holes in Medical Gloves

D5250 Specification for Poly(vinyl chloride) Gloves for Medical Application

D5712 Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method

D6124 Test Method for Residual Powder on Medical Gloves

D6319 Specification for Nitrile Examination Gloves for Medical Application

D6355 Test Method for Human Repeat Insult Patch Testing of Medical Gloves

D6499 Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products

D6977 Specification for Polychloroprene Examination Gloves for Medical Application

D6978 Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

D7102 Guide for Determination of Endotoxin on Sterile Medical Gloves

D7160 Practice for Determination of Expiration Dating for Medical Gloves

D7161 Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions

D7198 Specification for Disposable Embalming Gloves for Single-Use Applications

D7427 Test Method for Immunological Measurement of Four Principal Allergenic Proteins (Hev b 1, 3, 5 and 6.02) in Hevea Natural Rubber and Its Products Derived from Latex

D7558 Test Method for Colorimetric/Spectrophotometric Procedure to Quantify Extractable Chemical Dialkyldithiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators in Natural Rubber Latex and Nitrile Gloves

D7866 Specification for Radiation Attenuating Protective Gloves

D7907 Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves

[1] This guide is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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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.

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