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Title: Standards for Examination Gloves and Their Medical Applications – An ASTM-EN Comparison

Date/Time: 17 November, 2:30 PM (EEST)/7:30 AM (EST)

Presenter: Margaret Stephens, current chair of D11.40 on Consumer Rubber Products

About the Session

The impact of healthcare related infections is a global concern, and hands are a leading means of direct or indirect transport of infectious microorganisms. Medical practitioners use billions of rubber examination gloves each year. More than a dozen standards for these gloves are under the responsibility of ASTM International technical committee on rubber and rubber-like materials (D11), and more specifically, the subcommittee on consumer rubber products (D11.40). The standards specify rubber and nitrile medical gloves, among others, and help manufacturers and testers check for things like residual powder or holes. During this technical session, presenters from D11 will review four selected D11 standards and provide a comparison to several EN standards as follows:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D3578-19 Standard Specification for Rubber Examination Gloves
- ASTM D5250-19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- ASTM D6977-19 Standard Specification for Polychloroprene Examination Gloves for Medical Application

- EN 455-1 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
- EN 455-2 Medical gloves for single use - Part 2: Requirements and testing for physical properties
- EN 455-3 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
- EN 455-4 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

Learning Objectives

- Requirements for detection of holes
- A comparison of property requirements including chemicals, endotoxins, powders, leachability of proteins, and shelf life
- Tests for accelerated aging
- U.S. Food and Drug Administration requirements for import into the United States

Who Should Attend?

- Government authorities that regulate public health and the provision of protective products for both healthcare and the general public
- Government officials involved in the approval or clearance of examination gloves
- Manufacturers of examination gloves and related products
- Individuals involved the development of standards for manufacture of examination gloves or their use
- Members of organizations representing healthcare end users and other workers
- Professionals involved in research for disease transmission or individual protection