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EN Standards versus ASTM

Presented By: Margaret Stephens
Freedom of Holes

- ASTM D5151, Test method for Detection of Holes in Medical Gloves – Specification for holes found in individual glove standards
- ASTM D3577 – Standard Specification for Rubber Surgical Gloves
  - Freedom of Holes AQL 1.5
  - Freedom of Holes AQL 2.5
- EN 455-1 Exam Gloves
  - AQL 1.5
- EN455-1 Surgeon Gloves
  - AQL 0.65
### Physical Properties, before and after aging

- **All standards use 13 samples at a 4.0 AQL**
- **ASTM standards use ASTM D412**
- **ASTM gloves standards specify not to age gloves over six months for testing**
- **ASTM glove standards suggest the use of Die C and follows test method ASTM D412**
- **EN455-2 includes test method**

<table>
<thead>
<tr>
<th>Standard</th>
<th>Before Aging</th>
<th>Throughout Shelf life</th>
<th>After Aging</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tensile Strength</strong></td>
<td><strong>Stress at 500% Elongation (modulus)</strong></td>
<td><strong>Ultimate Elongation</strong></td>
<td><strong>Force at Break (N)</strong></td>
</tr>
<tr>
<td>ASTM D3577 – Standard Specification for Rubber Surgical Gloves Type 1 - Gloves compounded primarily from natural rubber latex.</td>
<td>24 MPa, minimum</td>
<td>5.5 MPa minimum</td>
<td>750% min</td>
</tr>
<tr>
<td>ASTM D3577 – Standard Specification for Rubber Surgical Gloves Type 2 - Gloves compounded from a rubber cement or from synthetic rubber latex.</td>
<td>17 MPa, minimum</td>
<td>7.0 MPa minimum</td>
<td>650% minimum</td>
</tr>
<tr>
<td>EN 455-2 – Requirements for all Surgical Gloves</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ASTM D 3578 – Standard Specification for Rubber Exam Gloves – Type 1 - Gloves with a minimum tensile strength of 18 MPa and a maximum stress at 500 % elongation of 5.5 MPa.</td>
<td>18 MPa, minimum</td>
<td>5.5 MPa minimum</td>
<td>650% minimum</td>
</tr>
<tr>
<td>ASTM D 3578 – Standard Specification for Rubber Exam Gloves – Type 2 - —Gloves with a minimum tensile strength of 14 MPa and a maximum stress at 500 % elongation of 2.8 MPa.</td>
<td>14 MPa minimum</td>
<td>2.8 MPa minimum</td>
<td>650% minimum</td>
</tr>
<tr>
<td>EN 455-2 – Requirements for all exam gloves, except polyvinyl chloride and polyethylene</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ASTM D6319 - Standard Specification for Nitrile Exam Gloves</td>
<td>14 MPa minimum</td>
<td>N/A</td>
<td>500% minimum</td>
</tr>
<tr>
<td>ASTM D6977 Standard Specification for Polychloroprene Exam Gloves</td>
<td>14 MPa minimum</td>
<td>N/A</td>
<td>500% minimum</td>
</tr>
<tr>
<td>ASTM D 5250 - Standard Specification for Poly(vinyl chloride) Exam Gloves</td>
<td>11 MPa minimum</td>
<td>N/A</td>
<td>300% minimum</td>
</tr>
<tr>
<td>EN 455-2 – Requirements for gloves made from thermos plastics (polyvinyl chloride and polyethylene)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
ASTM versus EN

• **Chemicals:**
  • EN455-3 and ASTM D3577 state the Gloves shall not free of talcum powder (magnesium silicate).

• **Endotoxins:**
  • EN455-3 states for gloves labeled as low endotoxin units per pair of gloves they shall not exceed 20 endotoxin per pair.
  • ASTM D 7103 lists the test method of ASTM D7102, Guide for Determination of Endotoxins on Sterile medical gloves and the requirements would be determined by the labeling claim.

• **Powder:**
  • Both ASTM and EN standards have the same specification for powder free gloves at 2.0 mg.
  • ASTM gloves standards list the maximum powder limit of 15 mg/dm² for powdered gloves.
  • EN455-3 states any gloves with more than 2.0 mg is a powdered glove, with no maximum.
  • EN455-3 references EN ISO 21171 clauses 7 and 8.

• **Proteins, leachable –**
  • ASTM D 3577 and 3578 glove standards references ASTM D5712, Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products using the Lowry Method. The gloves shall have a recommended aqueous soluble protein content limit of 200 µg/dm² in accordance with 8.7 and Annex A1, or have a recommended antigenic protein content limit of 10 µg/dm² in accordance with 8.9 and Annex A2.
  • EN455-3: The test method for the analytical determination of leachable protein shall be the modified Lowry method given in Annex A or a suitably validated method which has been correlated against the modified Lowry method. The manufacturer shall strive to minimize the leachable protein level.

• **Shelf Life Determination:**
  • ASTM Gloves standards do not list the methods.
  • ASTM D7103 lists theses standards:
    • ASTM D7160 – Standard Practice for Determination of Expiration Dating for Medical Gloves.
    • ASTM D7161 - Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Condition. Temperatures can be controlled or uncontrolled but must be specified.

• **EN455-4 – Medical gloves for single use - Part 4: Requirements and testing for shelf life determination. This standard list both methods:**
  • Method for the determination of shelf life by real time stability studies. 25 °C is the mean kinetic temperature for temperate climates.
  • Guidance on conducting and analyzing accelerated ageing studies. Guidance for selection of temperature is given in EN ISO 2578.

• **Accelerated aging temperature of 50° C is the same for both EN and ASTM standards.**