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EN Standards versus ASTM

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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
- ASTM D 3578- Standard Specification for Rubber Exam Gloves, ASTM D 5250 - Standard Specification for Poly(vinyl chloride) Exam Gloves, ASTM D6319 -Standard Specification for Nitrile Exam Gloves, ASTM D6977 Standard Specification for Polychloroprene Exam Gloves
  - 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 uses 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	Before Aging			Throughout Shelf life	After Aging	
	Tensile Strength	**Stress at 500% Elongation (modulus)**	**Ultimate Elongation**	**Force at Break (N)**	**Tensile Strength**	**Ultimate Elongation**
ASTM D3577 –Standard Specification for Rubber Surgical Gloves Type 1 - Gloves compounded primarily from natural rubber latex.	24 MPa, minimum	5.5 MPa minimum	750% min	N/A	18 MPa minimum	560% minimum
ASTM D3577 –Standard Specification for Rubber Surgical Gloves Type 2 - Gloves compounded from a rubber cement or from synthetic rubber latex.	17 MPa, minimum	7.0 MPa minimum	650% minimum	N/A	12MPa minimum	490% minimum
EN 455-2 – Requirements for all Surgical Gloves	N/A	N/A	N/A	≥ 9.0 (N)	N/A	N/A
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.	18 MPa, minimum	5.5 MPa minimum	650% minimum	N/A	14 MPa minimum	500% minimum
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.	14 MPa minimum	2.8 MPa minimum	650% minimum	N/A	14 MPa minimum	500% minimum
EN 455-2 – Requirements for all exam gloves, except polyvinyl chloride and polyethylene	N/A	N/A	N/A	≥ 6.0 (N)	N/A	N/A
ASTM D6319 -Standard Specification for Nitrile Exam Gloves	14 MPa minimum	N/A	500% minimum	N/A	14 MPa minimum	400% minimum
ASTM D6977 Standard Specification for Polychloroprene Exam Gloves	14 MPa minimum	N/A	500% minimum	N/A	14 MPa minimum	400% minimum
ASTM D 5250 - Standard Specification for Poly(vinyl chloride) Exam Gloves	11 MPa minimum	N/A	300% minimum	N/A	11 MPa minimum	300% minimum
EN 455-2 – Requirements for gloves made from thermos plastics (polyvinyl chloride and polyethylene)	N/A	N/A	N/A	≥ 3.6 (N)	N/A	N/A

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
  - ASTM glove standards reference ASTM D6124, Test Method for Residual Powder on Medical Gloves
  - 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.