Specifications on gloves

Medical gloves are classified as Class II devices, and must be licensed as such. This is the case whether the gloves are made of latex, vinyl, synthetic polymer or nitrile, or are sterile or non-sterile. For example, disposable, non-sterile, polyethylene gloves in first aid kits are medical gloves. They protect both the patient and the wearer.

The Canadian standard is for glove to be compliant to ISO 11193-1, or to ASTM D3578 depending on their material.

However, if a glove is EN 455 compliant, then it also meets the required standard.

Applicable standards

	Canada	USA	Europe
Standard	ISO 11193-1:2008 Single use medical examination gloves – Part 1: Specification for gloves made from rubber latex or rubber solution	ASTM D 3578:2005 Standard specification for rubber examination gloves	EN 455-1:2000 Freedom from holes EN 455-2:2009 Physical Properties EN 455-3:2006 Biological evaluation EN 455-4:2009 Shelf life determination

Although Canada requires gloves to meet requirements as laid out in ISO 11193-1:2008 standard, it can be noted that CGSB (Canadian General Standards Board) tests for powder residual (ASTM D6124) and protein (ASTM D6499) as well.

Each standard has its own specifications, but they cover:

	Freedom from holes	Dimensions	Physical properties	Protein leaching	Powder residue	Powder amount	Shelf life
ISO	X	X	X				
ASTM	X	X	X	X	X	X	
EN	X	X	X	X	X		X

Freedom from holes:

Standard	**Acceptable Quality Level**	**Volume of water (mL)**	**Observations**
ISO 11193-1	2.5%	1000 +/- 50	Immediately & after about 2 min
ASTM D3578	2.5%	Min 1000	Immediately & after about 2 min
EN 455-1	1.5%	1000 +/- 50	Immediately & after about 2 min

Acceptable Quality Level (% of glove failures per lot before rejecting the lot) of ISO and ASTM is 2.5%, while EN requires an AQL of 1.5%. They all use 1L of water, with observations immediately and after about 2 min.

Physical properties:

	Force at break (N)		Tensile strength (Mpa)		
Standard	**Unaged**	**Aged**	**Unaged**	**Aged**	**Cutter width**
ISO 11193-1	7.0	6.0	14.6	12.5	4.0 mm
ASTM D3578			18	14	N/A
EN 455-2	9.0	6.0	25	16.7	3.0 mm

For reference, since Government of Canada refers back to ISO 11193-1, and ASTM D3578-05, here are their respective specifications:

ISO 11193-1:2008 (E)- Type 1 (Sampling / Inspection by attributes: ISO 2859-1)					
Characteristic			**Testing Methodology**	**Acceptable Limits**	
Dimension & Tolerance	Width (mm)		ISO 11193-1	Extra-Small (XS)	≤ 80
				Small (S)	70 - 90
				Medium (M)	85 - 105
				Large (L)	100 - 120
				X-Large (XL)	≥ 110
	Length (mm)			XS & S: ≥ 220 Others: ≥ 230	
	Thickness (mm)	Palm		Smooth: 0,08-2,00	Textured: 0,11-2,03
		Finger		Smooth: ≥ 0,08	Textured: ≥ 0,11
Water tightness Test (Freedom from Holes)				As prescribed by Inspection Level and AQL	
Physical Requirement	Before ageing	Force at Break, N	ISO 37	≥ 7,0	
		Elongation at Break,%		≥ 650%	
	After ageing	Force at Break, N		≥ 6,0	
		Elongation at Break,%		≥ 500%	

ASTM D 3578-05, Type 1 (Sampling / Inspection by attributes: ISO 2859-1)					
Characteristic			**Testing Methodology**	**Acceptable Limits**	
Dimension & Tolerance	Width (mm)		ASTM D 3767	Extra-Small (XS)	60 - 80
				Small (S)	70 - 90
				Medium (M)	85 - 105
				Large (L)	101 - 121
	Length (mm)			XS & S: ≥ 220 Others: ≥ 230	
	Thickness (mm)	Palm		≥ 0,08	
		Finger			
Water tightness Test (Freedom from Holes)			ASTM D 5151	As prescribed by Inspection Level and AQL	
Physical Requirement	Before ageing	Tensile Strength	ASTM D 412	≥ 18MPa	
		Ultimate Elongation		≥ 650%	
	After ageing	Tensile Strength		≥ 14 MPa	
		Ultimate Elongation		≥ 500%	
Powder Residue	Powder Free Gloves		ASTM D 6124	≤ 2,0 mg/glove, Inspection Level N=5	
	Powdered Gloves			≤ 10,0 mg/dm^2, Inspection Level N=2	
Latex Protein	Aqueous Extractable Protein		ASTM 5712	≤ 200 µg/dm^2	
	Antigenic protein content		ASTM 6499	≤ 10 µg/dm²	

ISO 11193-1 and ASTM 3578-5 are further broken down in the following standards for testing:

	Nitrile	Vinyl	Latex
ASTM D6319 – Standard specification for Nitrile medical examination gloves	X		
ASTM D5250 – Standard specification for poly(vinyl chloride) medical exam gloves		X	
ASTM D412 – Standard test methods for vulcanized rubber and thermoplastic elastomers tension			X
ASTM D3767 – Standard practice for rubber measurement of dimensions			X
ASTM D3578 – Standard specification for rubber examination gloves			X
ASTM D6499-03 – Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products.			X
ASTM D412 – Standard test methods for vulcanized rubber and thermoplastic elastomers tension	X	X	X
ASTM D5151 – Standard test method for detection of holes in medical gloves	X	X	X
ASTM D6124 – Standard test method for residual powder on medical gloves	X	X	X
ASTM D6978 – Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs	X		
ASTM F1671 – Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 Bacteriophage penetration as a test system	X	X	X
ASTM F739 – Standard test method for permeation of liquids and gases through protective clothing materials under conditions of continuous contact	X	X	
ISO 21171:2006 Medical gloves — Determination of removable surface powder	X	X	X

ISO 11193-2:2006 Poly(vinyl chloride) Gloves for medical applications		X	

Acceptance Criteria

Medical gloves must comply with the following criteria:

1. Material
    - Natural Rubber Latex - ISO 11193-1:2008, type 1 or ASTM D 3578:2005 or EN 455-1 and EN 445-2
    - Nitrile Rubber Latex - ISO 11193-1:2008, type 2 or ASTM D 6319:2019 or EN 455-1 and EN 445-2
    - Poly(vinyl chloride) - ASTM D5250-06 (2011) or ISO 11193-2:2006
2. Quality management systems — Requirements for regulatory purposes:
    - Vendors/manufacturers must be ISO 13485:2016 certified.
3. Acceptable documents:
    - Compliance certifications
    - Product test reports. The laboratories must be accredited to ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories) by the Standards
    - Council of Canada (SCC) or other accreditation organizations with which the SCC has signed a Mutual Recognition Agreement. The test reports must be less than 12 months old.