

HALYARD* AQUASOFT* NITRILE



Exam Gloves

TEST & TECHNICAL DATA	TEST	OBJECTIVE	RELEVANCE	DESCRIPTIONS	FDA REQUIREMENT (EFF. 12/08)	ASTM REQUIREMENT	HALYARD* REQUIREMENT	AQUASOFT* TARGET
PHYSICAL PROPERTIES	ASTM D 5151 Detection of Holes in Medical Gloves (Water Leak) [†]	Determine acceptability of gloves with respect to freedom from holes. The lower the Acceptance Quality Level (AQL), the better.	Measures potential for glove barrier integrity failure using ASTM standards.		Pass @ 2.5 AQL	Pass @ 2.5 AQL	Pass @ 1.0 AQL	Pass @ 1.0 AQL
	ASTM D 412 Standard Test method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (Tensile Strength) [†]	To assess the amount of force applied to a glove until it breaks. The lower the Acceptance Quality Level (AQL), the better.	The lower the tensile strength, the more easily materials of the same thickness can break when snagged or pressure is applied.	Before Aging After Aging	14 MPa 14 MPa (4.0 AQL)	14 MPa 14 MPa (4.0 AQL)	14 MPa 14 MPa (2.5 AQL)	23 MPa 28 MPa (2.5 AQL)
	ASTM D 412 Standard Test method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (Ultimate Elongation) [†]	The ability to stretch a glove until it breaks. The lower the Acceptance Quality Level (AQL), the better.	Stretchability is very important at the microscopic level where the glove material must be able to give rather than break when stressed or snagged by instruments, fingernails, ridges on caps, twisting stop cocks on IV sets, or snapping off enclosures.	Before Aging After Aging	500% 400% (4.0 AQL)	500% 400% (4.0 AQL)	500% 400% (2.5 AQL)	500% 450% (2.5 AQL)
	ASTM D 3767 Standard Practice for Rubber-Measurement of Dimensions (Thickness) [†]	Thickness is measured in millimeters (mm) utilizing a micrometer at specified locations on the finger and palm. The lower the Acceptance Quality Level (AQL), the better.	Thickness is a metric that can be used in determining both tactile sensitivity and barrier protection. Consistency for this metric is key for both durability and chemical permeation protection.	Finger Palm Cuff	0.05mm 0.05mm (4.0 AQL)	0.05mm 0.05mm (4.0 AQL)	0.05mm 0.05mm (2.5 AQL)	0.08mm 0.07mm (2.5 AQL)
	ASTM D 3767 Standard Practice for Rubber-Measurement of Dimensions (Length) [†]	Length is measured in millimeters (mm) utilizing a rule or tape from the upper finger tip to cuff. The lower the Acceptance Quality Level (AQL), the better.	This measurement helps ensure appropriate length and size correctness.	U.S. Requirements	230 mm (4.0 AQL)	230 mm (4.0 AQL)	230 mm (2.5 AQL)	242 mm (2.5 AQL)
	ASTM D 6124 Residual Powder on Medical Gloves	Determine amount of residual powder on the glove surface; ASTM specifies the maximum allowed level of filter-retained substances for a powder-free claim.	A powder-free glove helps reduce powder-associated wound healing complications caused by starch glove powder and helps reduce irritant reactions and the transfer of proteins and chemicals that could potentially result in Type IV or I reactions.		<2mg		<2mg	<2mg
SYSTEM BIOCOMPATIBILITY	Systemic Toxicity ISO 10993-11	Evaluate the potential for harmful effects to organs or systems using specific product extracts.	Reduce risk of adverse systemic and local response due to contact with product.		Optional		Pass	Pass

HALYARD* AQUASOFT* Nitrile Powder-Free Exam Gloves have been tested according to the tests listed above.
[†] D6319-10a Standard Specification for Nitrile Examination Glove for Medical Applications

HALYARD* AQUASOFT* NITRILE

Exam Gloves

TEST & TECHNICAL DATA	TEST	OBJECTIVE	RELEVANCE	DESCRIPTIONS	FDA REQUIREMENT (EFF. 12/08)	ASTM REQUIREMENT	HALYARD* REQUIREMENT	AQUASOFT* TARGET
IRRITATION AND SENSITIZATION	PRIMARY Skin Irritation ISO-10993-10	Estimate the potential to induce skin irritation from direct exposure.	Measures the likelihood of the patient experiencing dermal irritation.		Pass		Pass	Pass
	Sensitization ISO-10993-10	Estimate the potential to induce contact sensitization Type IV delayed hypersensitivity immunological response via product extracts.	Decrease the likelihood of adverse immunological dermal response from product use over time.		Pass		Pass	Pass
RESIDUAL CHEMICALS	High Pressure Liquid Chromatography (HPLC)	Measure the type and amount of residual chemicals left on the glove.	Lower levels of residual chemicals decrease the risk of developing irritant and Type IV reactions.		Optional		Pass	Pass
VIRAL PENETRATION	Penetration by Bloodborne Pathogens Using Phi-X174 Bacteriophage (Viral Penetration) ASTM F 1671-97b	Measure the resistance of materials used in protective apparel to penetration by bloodborne pathogens.	Measures resistance to potentially infectious body fluids permeating through the protective material.		Optional	Pass	Pass	Pass
BARRIER	Resistance of Protective Materials to permeation by Liquids ASTM F 739 Gluteraldehyde 4% [‡]	Determine the level of barrier protection against Gluteraldehyde, which is commonly used in a healthcare setting.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.		Optional		Data on File	>480 min.
	Resistance of Protective Materials to permeation by Liquids ASTM F 739 Formaldehyde 10% [‡]	Determine the level of barrier protection against Formaldehyde, which is commonly used in a healthcare setting.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.		Optional		Data on File	>480 min.
	Resistance of Protective Materials to permeation by Liquids ASTM F 739 Povidone Iodine 10% [‡]	Determine the level of barrier protection against Povidone Iodine, which is commonly used in a healthcare setting.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.		Optional		Data on File	>480 min.
	Resistance of Protective Materials to permeation by Liquids ASTM F 739 Quaternary Detergent [‡]	Determine the level of barrier protection against Quaternary Detergent, which is commonly used in a healthcare setting.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.		Optional		Data on File	>480 min.

HALYARD* AQUASOFT* Nitrile Powder-Free Exam Gloves have been tested according to the tests listed above.

[‡] Testing was conducted on single layer glove material.