HALYARD* STERLING SG*

Nitrile Powder-free Exam Gloves

HALYARD

TEST & TECHNICAL DATA	TEST	OBJECTIVE	RELEVANCE	FDA REQUIREMENT	ASTM REQUIREMENT	HYH REQUIREMENT	DESCRIPTIONS	STERLING SG* RESULTS/TARGET
PHYSICAL PROPERTIES	ASTM D5151 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.	2.5 AQL	2.5 AQL	1.0 AQL		1.0 AQL
	ASTM D412 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.	4.0 AQL	4.0 AQL	4.0 AQL	Before Aging After Aging	35 MPa 38 MPa
	ASTM D412 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.	4.0 AQL	4.0 AQL	4.0 AQL	Before Aging After Aging	580% 550%
	ASTM 3767 Standard Practice for Rubber-Measurement of Dimensions (Thickness)	Thickness is measured in millimeters (mm) utilizing a micrometer at specified locations on the finger, palm, and cuff. 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.	4.0 AQL	4.0 AQL	4.0 AQL	Finger Palm Cuff	0.09 mm 0.07 mm 0.06 mm
	ASTM 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.	4.0 AQL 230 mm	4.0 AQL 230 mm	4.0 AQL 242 mm	U.S.	4.0 AQL 242 mm
	ASTM 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		<2mg; Pass
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
FOOD HANDLING	Meets the requirements of: 1) 21 CFR 177.2600 2) 21 CFR 180.22 - Acrylonitrile Copolymers	To ensure that nitrile gloves can be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.	Gloves that meet these requirements are safe to use in food handling activities.	Optional		Pass		Pass

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†D6319-00a Standard Specification for Nitrile Examination glove for Medical Applications

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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 adverseimmunological dermal response from product use over time	Yes		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 F1671-97b	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.	Pass		Pass		Pass
BARRIER	Resistance of Protective Materials to permeation by Liquids ASTM F739 Formalin - 10%	Determine the level of barrier protection against Formalin, which is commonly used in a healthcare setting.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.			Specific breakthrough times on record		>480 min.
	Resistance of Protective Materials to permeation by Liquids ASTM F739 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.			Specific breakthrough times on record		>480 min.
	EN 374-3 Norm Sodium Hydroxide (NaOH) - 40%	Determine the level of barrier protection against sodium hydroxide commonly used in a healthcare setting.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.				European Norm	Class 4 >120 min.
	EN 374-3 Norm Ethydium Bromide - 0.4%	Determine the level of barrier protection against chemicals commonly used in a health care setting.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.				European Norm	Class 6 >240 min.

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For more information, please contact your sales representative or visit our website at www.halyardhealth.com.