

INTERCEPT FREE

MANUFACTURING SPECIFICATION DATASHEET

GENERAL PRODUCT DESCRIPTION

MATERIAL	LENGTH	FT THICKNESS	PROCESS	SURFACE	CUFF/FIT
Nitrile, Accelerator, Sulfur & Zinc Free, Examination Grade, White/Green	12"/302 mm Minimum	8.25 Mil/.21 mm	Interior Surface Accelerator, Sulfur & Zinc Free Polymer Coated Powder Free	Textured Fingertips/ RezTak-No Stick Surface	Beaded/ Ambi

FENTANYL & HEROIN PERMEATION TESTED

FENTANYL & HEROIN 3RD PARTY TESTED – SEE ADDENDUM

Contact the PH&S Products LLC main office at 888.688.6768 or sales@phs-products.com for addendum.

CERTIFICATIONS / TEST STANDARDS

STANDARD / NUMBER	TITLE
NFPA 1999-2018	National Fire Protection Agency Standard on Protective Clothing & Ensembles for Emergency Operations
ASTM D6319	Standard Specification for Nitrile Exam Gloves
ASTM D412a	Vulcanized Rubber & Thermoplastic Elastomers - Tension 1
ASTM D412a (NFPA Modification)	Ultimate Elongation Percentage Following 100% Isopropanol Soak for 2 Hours
ASTM D573	Standard Test Method for Rubber - Deterioration in an Air Oven
ASTM D573 (NFPA Modification)	Ultimate Elongation Percentage Following Heat Aging at 70°C for 166 Hours
ASTM F1671	Standard Test Method for Detection of Holes in Medical Grade Gloves
ASTM F1342	Standard Test Method for Protective Clothing Material Resistance to Puncture
ASTM D5151	Standard Test Method for Detection of holes in Medical Grade Gloves
NFPA Dexterity Test	Crawford Small Parts Dexterity Test, Screws Technique
ASTM D7558-09	Standard Test Method for Extractable Accelerators
ASTM D6124	Standard Test Method for Residual Powder on Medical Gloves
ASTM D6978	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Manufactured under GMP, ISO 9001, ISO 13485 and CMDCAS Quality System

PHYSICAL DIMENSIONS AND TOLERANCES

DESIGNATION	TOLERANCE	S	M	L	XL	2XL	3XL
Width (mm)	±3	85	95	105	115	124	130
Length (mm)	±2	302	302	302	302	302	302
Thickness Single Wall (mm) Finger	±.02	0.21	0.21	0.21	0.21	0.21	0.21
Thickness Single Wall (mm) Palm	±.02	0.14	0.14	0.14	0.14	0.14	0.14
Thickness Single Wall (mm) Cuff	±.02	0.11	0.11	0.11	0.11	0.11	0.11

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PERFORMANCE REQUIREMENTS - SAMPLING PLAN

ALL PRODUCT TO BE SAMPLED IN ACCORDANCE TO ANSI / ASQ Z1.4-2008

LOT & BATCH CONTROL:	LOT SIZE	NTE 900,000	BATCH SIZE	NTE 40,000
CHARACTERISTIC	RELATED DEFECT		INSPEC. LEVEL	AQL
Watertight	Holes - Pinholes		G-1	0.65
Dimensions	Width, Length, Thickness		S-2	4.0
Physical Properties	Before, After Aging		S-2	4.0
Visual Defects Major	Rips or tears, visible holes, sticking pleats (>10mm), embedded foreign matter (>5mm), large lumps, permanent dirt, torn beads and or cuffs, extreme thin spots, improper size, stickiness		G-1	2.5
Visual Defects Minor	Stains and discoloration, sticking pleats (<10mm), embedded foreign matter (<5mm), small lumps, removeable dirt, defective beads		G-1	4.0

PHYSICAL REQUIREMENTS

TEST METHOD	TOLERANCE	TENSILE (MPa) +/-3		ELONGATION +/-5%	
		BEFORE	AFTER	BEFORE	AFTER
ASTM D412a / D573	MIN	30	32	600%	550%
ASTM D412a NFPA IPA SOAK	MIN			550%	
EN 388 Force at Break (n)	+/- 3		14n		

PACKAGING AND MARKING REQUIREMENTS

GENERAL REQUIREMENTS

- Each carton and inner box must be labeled with size, lot/batch number, PH&S Products LLC name and address, country of origin, product description and date of manufacture.
- Each box contains 100 Gloves by weight S – L and 90 Gloves by weight XL – 3XL / 10 Boxes per Case
- Each carton and inner box must conform to NFPA 1999 (2018) labeling requirements.
- All cases and boxes must be printed clearly.
- Inner box to be 450 gram weight box, dual fold, able to withstand box ends opening during use. Outer carton to be a standard corrugated box and must be able to withstand crushing during container stacking and subsequent shipment.

STORAGE AND SHELF LIFE REQUIREMENTS

- SHELF LIFE: If product is stored optimum storage condition listed below, then product shelf life shall be no less than 5 years.
- STORAGE TEMPERATURE: No minimum temperature required. Do not store in temperatures >110° F or in damp/high humidity areas.
- OPTIMUM STORAGE CONDITIONS: Temperature controlled environment with no exposure to direct sunlight.

CERTIFICATIONS

21 CFR	DEVICE LISTING NO.	510K NO.	UL NO.
Meets 21 CFR 880.6250 Patient Examination Glove Requirement	D026154	K990541	PRIVATE LABELER: MH48780