Sterling* Nitrile XTRA*

Examination Glove – non-sterile

TECHNICAL DOCUMENT

CE

Description

44286 Sterling* Nitrile Xtra* XS
44287 Sterling* Nitrile Xtra* S
44288 Sterling* Nitrile Xtra* M
44289 Sterling* Nitrile Xtra* L
44290 Sterling* Nitrile Xtra* XL

Non-powdered, textured finger tips, ambidextrous, optimized. Color: Grey.

Dimensions:

	Palm width	Length
Extra Small (XS)	70 mm	310 mm
Small (S)	80 mm	310 mm
Medium (M)	95 mm	310 mm
Large (L)	110 mm	310 mm
Extra Large (XL)	120 mm	310 mm

Properties:	**HALYARD (Minimum Results/Specification Target)**	**EN/ ASTM requirement/Test Method**
Median force at break before aging (Newton)	**10.0 N**	EN 455-2: 6N
Median force at break after aging (Newton)	**9.0 N**	EN 455-2: 6N
Residual powder mg/glove	**1.0 mg (3x rinsed)**	EN 455-3/ ISO 21171/ASTM D6124: <2.0 mg
Material Thickness	**Thickness middle finger: 0.12 mm** **Thickness palm: 0.09 mm** **Thickness cuff: 0.07 mm**	--
Tensile Strength ASTM D6319	**42 MPa Before Aging (2.5 AQL)** **38 MPa After Aging (2.5AQL)**	Test Method ASTM D412: 14 MPa (4.0 AQL)
Ultimate Elongation ASTM D6319	**550% Before Aging (2.5 AQL)** **550% After Aging (2.5 AQL)**	Test Method ASTM D412: 500% Before aging 400% After aging (4.0 AQL)
Detection of Holes in Medical Gloves ASTM D5151 Freedom of pinholes	**1.0 AQL**	ASTM D5151: AQL 2.5 EN 455-1: 1.5 AQL

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Indication

To protect patient and user from cross-contamination.

Counter indication

Not intended for applications involving direct exposure to harsh chemicals, where heavy duty industrial gloves are required.

Main Materials

Base material: Nitrile Butadiene.
Accelerators: ZDEC (ZINC DIETHYLDITHIOCARBAMATE) with residual concentrations <100 µg per gram.
Not intentionally formulated or treated with any of the following: Bisphenol A, colophony (rosin), natural rubber latex, brominated flame retardants, phthalates (DBP, BBP, DEHP, DMEP, DNOP, DPP, DIPP, DIDP, DINP), thiurams, mercaptobenzothiazole, thiourea, 1,3-diphenylguanidine, cetylpyridinium chloride, casein, (p)-phenyl endiamines.

Skin Friendly

Biocompatibility testing – Medical Devices	HALYARD
Biocompatibility testing in accordance with the ISO 10993-1 ▪ ISO 10993-11 (acute systemic toxicity) ▪ ISO 10993-10 (sensitization) ▪ ISO 10993-23 (irritation)	**Pass**

Residual Chemicals

High Pressure liquid Chromatography (HPLC)	HALYARD
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.	Rinsed 3x to reduce harmful chemicals to below detectable levels. ZDEC (ZINC DIETHYLDITHIOCARBAMATE) with residual concentrations <100 µg per gram.

Sterilization

Products are non-sterile.

Packaging

44286, 44287, 44288, 44289, and 44290: Shipping case of 1000 units.
10 dispenser boxes of 100 units in each shipping case.

Bar coding: GS1-128 symbology, linear, on shipping case and dispenser box.

Dimensions	Length	Breadth	Height
Dispenser Box (mm)	270	130	65
Shipping Case (mm)	335	267	280

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EAN

Item	Description	AUn	EAN/UPC
44286	STERLING NITRILE-XTRA Exam Gloves XS	Sell Unit Package	30680651442865
44286	STERLING NITRILE-XTRA Exam Gloves XS	Inner Package	20680651442868
44287	STERLING NITRILE-XTRA Exam Gloves S	Sell Unit Package	30680651442872
44287	STERLING NITRILE-XTRA Exam Gloves S	Inner Package	20680651442875
44288	STERLING NITRILE-XTRA Exam Gloves M	Sell Unit Package	30680651442889
44288	STERLING NITRILE-XTRA Exam Gloves M	Inner Package	20680651442882
44289	STERLING NITRILE-XTRA Exam Gloves L	Sell Unit Package	30680651442896
44289	STERLING NITRILE-XTRA Exam Gloves L	Inner Package	20680651442899
44290	STERLING NITRILE-XTRA Exam Gloves XL	Sell Unit Package	30680651442902
44290	STERLING NITRILE-XTRA Exam Gloves XL	Inner Package	20680651442905

Manufacturing

Products are manufactured in Thailand/Malaysia. The quality system of the manufacturing sites are ISO 13485 and ISO 9001 compliant.

Regulatory information

- Product CE marked as per Regulation (EU) 2017/745 on Medical Devices. Class of the device: I.
- Product CE marked as per (EU) 2016/425 regulation on Personal Protective Equipment. Class of the equipment: PPE Category III
- Comply with EN 455-1, EN 455-2, EN 455-3, EN 455-4 +A1:2022
- Comply with EN ISO 21420,
- Comply with EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1
- Comply with ISO 16604
- Approved for Food Contact as per Regulation 1935/2004 and 10/2011.

Medical Device Class I
CE 2797
(PPE Cat. III)
UK CA
0086

AQL	HALYARD	EN 455-1 requirement
Freedom from pinholes	**1.0** **33% less defects per lot than EN 455 standard**	1.5

EN ISO 374-5 Microorganism risks	HALYARD
Resistance to bacteria and fungi	**Pass**
Resistance to virus	**Pass (ISO 16604 and ASTM F1671)**

- **EN 374-1 Type B (J K T) -** EN 16523-1:2015+A1:2018

Chemical	Permeation Test EN 16523-1:2015+A1:2018		Degradation Test EN ISO 374-4:2019
	Minimum Breakthrough Time (min)	Performance Level	Degradation (%)
Formaldehyde, 37% (T)	> 480	6	25.1
n-Heptane, 99% (J)	37.7	2	60
Sodium Hydroxide, 40% (K)	> 480	6	- 11.9

Performance levels according to EN ISO 374-1:2016 +A1:2018	1	2	3	4	5	6
Measured breakthrough times (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.
NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

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Storage

Store in a dry and cool place, away from intense sources of heat and sources of radiation.
Keep as much as practicably possible in its shipper box.

Shelf life

5 years, from the date of manufacture.

Chemotherapy/Chemicals

At O&M Halyard, we seek to constantly improve upon the quality of healthcare products and services available in the marketplace. We strive to deliver clinically superior products with remarkable service to improve the wellbeing of the people we touch every day. In accordance with this vision, we want to inform our customers of additional chemical and chemotherapy drug testing performed on our **Sterling* Nitrile XTRA * Powder-Free Exam Gloves**. In the US, the Food and Drug Administration requires submission and clearance of a premarket notification for medical exam gloves that are intended for use with chemotherapy drugs and requires glove products to be labeled with drugs tested and breakthrough times. Package labeling for Halyard exam gloves sold in the US meet this labeling requirement. Although additional chemotherapy drug and chemical testing is not required, Halyard believes the more informed our customers are, the better they will be able to understand the appropriate use of our products. The following chemotherapy drugs and chemicals have been tested according to EN374-1 (EN 16523-1 where applicable), ASTM D6978 (chemotherapy drugs) and ASTM F739 (chemicals). This data is provided for your information but is not intended to expand the intended use of the products beyond the scope of what has been cleared by the FDA or covered by the safety and performance requirements of the CE certification and European harmonized standards.

Chemotherapy Testing Information - Permeation testing per ASTM D6978

Chemotherapy Drugs Tested	Breakthrough time (minutes) Sterling Nitrile* XTRA*
Arsenic Trioxide (1 mg/ml)	>240
Azacitidine (25 mg/ml)	>240
Bendamustine (5 mg/ml)	>240
Bortezomib (1 mg/ml)	>240
Bleomycin sulfate (15 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Carboplatin (10 mg/ml)	>240
Carfilzomib (10 mg/ml)	>240
Carmustine (3.3 mg/ml)	25.2
Capecitabine (26 mg/ml)	>240
Cladribine (1 mg/ml)	>240
Cetuximab (Erbitux) (2 mg/ml)	>240
Cisplatin (1 mg/ml)	>240
Cyclophosphamide (20 mg/ml)	>240
Cytarabine HCL (100 mg/ml)	>240
Cyclosporin (100 mg/ml)	>240
Cytovene (Ganciclovir) (10 mg/ml)	>240
Dacarbazine (10 mg/ml)	>240
Dactinomycin (0.5 mg/ml)	>240
Daunorubicin HCL (5 mg/ml)	>240
Decitabine (5 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Doxorubicin HCL (2 mg/ml)	>240
Ellence (2 mg/ml)	>240
Epirubicin (2 mg/ml)	>240
Eribulin Mesylate (0.5 mg/ml)	>240
Etoposide (20 mg/ml)	>240
Fludarabine (25 mg/ml)	>240

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Chemotherapy Drugs Tested	Breakthrough time (minutes) Sterling Nitrile* XTRA*
Fluorouracil (50 mg/ml)	>240
Fulvestrant (50 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
Idarubicin (1 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Leuprolide Acetate Salt (5 mg/ml)	>240
Mechlorethamine HCL (1 mg/ml)	>240
Melphalan (5 mg/ml)	>240
Methotrexate (25 mg/ml)	>240
Mitomycin (0.5 mg/ml)	>240
Mitoxantrone (2 mg/ml)	>240
Oxaliplatin (2 mg/ml)	>240
Paclitaxel (6 mg/ml)	>240
Paraplatin (10 mg/ml)	>240
Pemetrexed (25 mg/ml)	>240
Pertuzumab (30 mg/ml)	>240
Raltitrexed (0.5 mg/ml)	>240
Retrovir (Zidovudine) (10 mg/ml)	>240
Rituximab (10 mg/ml)	>240
Sorafenib Tosylate (200 mg/ml)	>240
Tamoxifen (2 mg/ml)	>240
Temsirolimus (25 mg/ml)	>240
ThioTEPA (10 mg/ml)	35.5
Topotecan HCL (1 mg/ml)	>240
Trastuzumab (21 mg/ml)	>240
Trisenox (1 mg/ml)	>240
Triclosan (3 mg/ml)	>240
Vinblastine (1 mg/ml)	>240
Vincrinstine Sulfate (1 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240
Zoledronic Acid (0.8 mg/ml)	>240

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Additional Chemical Testing Information – ASTM F739/EN 374-1: EN 16523-1 (where applicable)

Chemicals Tested	CAS #	Test Method	Breakthrough time (minutes) Sterling* Nitrile
Adhesive Tape Remover Pads		ASTM F739	37.3
Alcoholic Bouin's Fixative		ASTM F739	42.0
Alcoholic Eosin		ASTM F739	8.0
Bleach	7681-9	ASTM F739	> 480
Bouin's Fixative		ASTM F739	> 480
B-Plus Fixative		ASTM F739	> 480
CarNoy's Fluid		ASTM F739	0
Cidex 14-Day		ASTM F739	> 480
Cidex OPA		ASTM F739	86.7
Decalcifier I		ASTM F739	> 480
EM Fixative		ASTM F739	> 480
Eosin Stain		ASTM F739	42.0
Ethyl Alcohol (95%)	64-17-5	ASTM F739	8.0
Ethanol (80%)	64-17-5	ASTM F739	8.0
Formalin Alcohol (tested for Formaldehyde)		ASTM F739	20.0
Formalin Alcohol (tested for Reagent Alcohol)		ASTM F739	16.0
Formalin, 10% Buffered (tested for Formaldehyde)	50-00-0	ASTM F739	> 480
Formalin, 10% Buffered (tested for Methanol)	50-00-0	ASTM F739	> 480
Giemsa Stain Solution		ASTM F739	19.3
Glutaraldehyde, 4%	111-30-8	ASTM F739	> 480
Haematoxylin Stain (Harris Solution)		ASTM F739	180.0
Hydrochloric Acid, 35.5%	7647-01-0	ASTM F739	91.0
Hydrogen Peroxide, 3%	7722-84-1	ASTM F739	> 480
Isopropyl Alcohol, 70%	67-63-0	ASTM F739	21.3
Methanol	67-56-1	ASTM F739	8.0
Methyl Methacrylate (Bone Cement)	80-62-6	ASTM F739	0
Monsel's Solution	1310-45-8	ASTM F739	> 480
OxyCide Concentrate		ASTM F739	40.0
OxyCide Ready to Use		ASTM F739	> 480
Permaslip Mounting Medium & Liquid Cover Slip		ASTM F739	0
Rapid Bone Decalcifier		ASTM F739	> 480
Reagent Alcohol	64-17-5	ASTM F739	10.7
Resert XL HLD		ASTM F739	13.3
Sodium Hydroxide (40%)	1310-73-2	ASTM F739	> 480
Sodium Hypochlorite, 10-13%	7681-52-9	ASTM F739	> 480
Trichloroacetic Acid, (10%)	76-03-9	ASTM F739	> 480
Xylene, (99%)	1330-20-7	ASTM F739	0
Acetone	67-64-1	EN 16523	< 5
Acetonitrile (99%)	79-06-1	EN 16523	0.5
Acetic acid (99%)	64-19-7	EN 16523	< 5
Ammonium Hydroxide (25%)	1336-21-6	EN 16523	20.8
Diethylamine (99%)	109-89-7	EN 16523	0
Ethyl Acetate	141-78-6	EN 16523	< 5
Ethidium bromide (1%)	1239-45-8	EN 16523	> 480
Ethanol (70%)	64-17-5	EN 16523	20
Isopropyl Alcohol, 70%	67-63-0	EN 16523	32
Hydrochloric Acid, 30%	7647-01-0	EN 16523	> 480
Hydrogen Peroxide (30%)	7722-84-1	EN 16523	45.7
Nitric acid (65%)	7697-37-2	EN 16523	< 5
Sulfuric Acid (50%)	7664-93-9	EN 16523	> 480
Sulfuric Acid (96%)	7664-93-9	EN 16523	< 5
Fentanyl Citrate Injection, 100 µg/2ml	990-73-8	ASTM 06978-05	> 240

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Sustainability

ISO 14001:2015 - Environmental management systems	
The HALYARD* manufacturing facility is purpose designed, using 92% renewable energy, from sustainable by-products of rubber tree plantations, instead of fossil fuels, as part of the manufacturing process.	GLOVES MADE WITH 92% RENEWABLE ENERGY
Patented nitrile exam glove dispensers and cartons, made with up to 95% recycled material.	PACKAGING MADE WITH UP TO 95% RECYCLED MATERIAL
Thailand labor management excellence award This award is part of an initiative to recognize and encourage outstanding practices in labor management within Thai companies and organizations. The goal is to promote better working conditions, enhance the quality of life for workers, and increase productivity by highlighting organizations that demonstrate excellence in various aspects of labor management.	SAFESKIN* LABOR MANAGEMENT EXCELLENCE AWARD 2019-2023
Eco Factory Gold+ Award is a recognition under the "Eco Factory" program in Thailand, aimed at encouraging and honoring factories that achieve exceptional environmental performance. This award is part of a broader initiative by the Federation of Thai Industries (FTI) and the Ministry of Industry to promote sustainable industrial practices.	SAFESKIN* ECO FACTORY GOLD+ AWARD 2020
The Green Industry Level 5 Award is the highest level of recognition in Thailand's Green Industry initiative, which is administered by the Ministry of Industry. This award is designed to honor companies that demonstrate the highest commitment to environmental sustainability and integrate eco-friendly practices across every aspect of their business operations.	SAFESKIN* GREEN INDUSTRY LEVEL 5 AWARD 2023
Economical packaging HALYARD* Nitrile Exam Gloves: Offer up to a 5 YEAR SHELF LIFE	IDEAL FOR STOCKPILING

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