

pure[11]-Nr.: 1105353, Marke:

Eigenschaften

Empfohlene Reinraumklassen

ISO

GMP

pure[11] GmbH |
Bavariafilmplatz 7 | D-82031 Grünwald
T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

we care

Material

-

Verpackung

- Box

Produktvarianten

pure¹¹-Nr.: 1105353,

pure¹¹-Nr.: 1105353GNL, Nitril-Handschuhe PUREZERO LIMON #LFS311LG

Farbe: Grün; Größe: L / VE: 2000STK

pure¹¹-Nr.: 1105353GNM, Nitril-Handschuhe PUREZERO LIMON #LFS311MD

Farbe: Grün; Größe: M / VE: 2000STK

pure¹¹-Nr.: 1105353GNS, Nitril-Handschuhe PUREZERO LIMON #LFS311SM

Farbe: Grün; Größe: S / VE: 2000STK

pure¹¹-Nr.: 1105353GNXL, Nitril-Handschuhe PUREZERO LIMON #LFS311XL

Farbe: Grün; Größe: XL / VE: 1700STK

pure¹¹-Nr.: 1105353GNXS, Nitril-Handschuhe PUREZERO LIMON #LFS311XS

Farbe: Grün; Größe: XS / VE: 2000STK

HALYARD*

HALYARD* **PURE**ZERO* LIMON* and LIMON-XTRA* Nitrile Exam Gloves

For Medical/Industrial/Lab Use

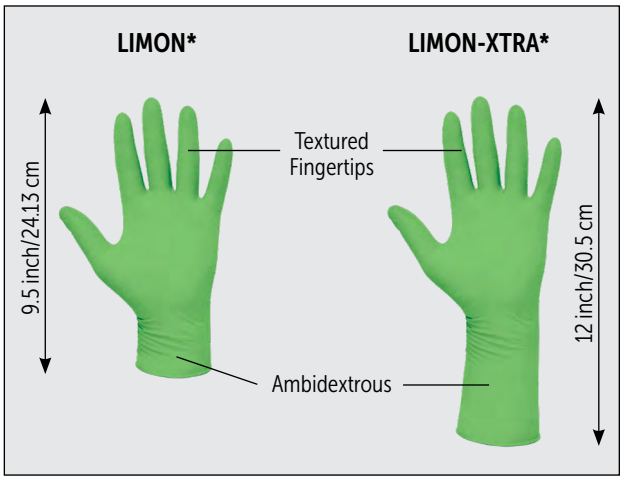
TECHNICAL DATA SHEET

Tested against Fentanyl & Xylazine.

Meets USP <800> Guidelines.

Description

HALYARD* **PURE**ZERO* LIMON* (9.5") and LIMON-XTRA* (12") Nitrile Exam Gloves are designed for use in laboratories, research environments and clean areas with applications in pharmaceutical, medical device manufacturing, biotechnology and food processing/handling. HALYARD* **PURE**ZERO* LIMON* and LIMON-XTRA* Nitrile Exam Gloves are tested for use against 57 chemicals and 18 chemotherapy drugs. The beaded cuff allows for ease of donning, and textured fingertips provide tactile agility.



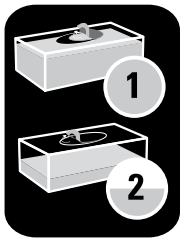
Manufactured at OUR OWN Safeskin Facility in Thailand.

Physical Properties

AQL	1.0
Non-Sterile	✓
Ambidextrous	✓
Textured Fingertips	✓
Not Made With Natural Rubber Latex	✓
Powder-Free	✓
Tensile Strength[1]	42 MPa (Target)
Ultimate Elongation[1]	650%
Shelf Life	3 Years

SMARTPULL* Dispenser

PUREZERO* LIMON* gloves have a SMARTPULL* Dispenser, which incorporates two separate openings on the box. The first, smaller opening is used when the box is full to control dispensing and lessen waste. When the box is half empty, the second, larger opening allows easier access to the gloves.



Glove Dimensions

	X-SMALL	SMALL	MEDIUM	LARGE	X-LARGE
LIMON* Glove Length (inch/cm)	9.5"/24	9.5"/24	9.5"/24	9.5"/24	9.5"/24
LIMON-XTRA* Glove Length (inch/cm)	12"/30.5	12"/30.5	12"/30.5	12"/30.5	12"/30.5
Middle Finger Length (mm)	71	78	84	87	96
Width of Palm (mm)	70	80	95	110	120
Fingertip Thickness	0.12 mm (4.7 mil)	0.12 mm (4.7 mil)	0.12 mm (4.7 mil)	0.12 mm (4.7 mil)	0.12 mm (4.7 mil)
Palm Thickness	0.09 mm (3.5 mil)	0.09 mm (3.5 mil)	0.09 mm (3.5 mil)	0.09 mm (3.5 mil)	0.09 mm (3.5 mil)
Cuff Thickness	0.07 mm (2.8 mil)	0.07 mm (2.8 mil)	0.07 mm (2.8 mil)	0.07 mm (2.8 mil)	0.07 mm (2.8 mil)

HALYARD

HALYARD* **PURE**ZERO* LIMON* and LIMON-XTRA* Nitrile Exam Gloves

For Medical/Industrial/Lab Use

TECHNICAL DATA SHEET

Ordering Information

Product Name	Code	Size	Box Qty.	Case Qty.
HALYARD* **PURE**ZERO* LIMON* Nitrile Exam Gloves - 9.5"/24cm Length	LFS311XS	XS	200	2000
	LFS311SM	S	200	2000
	LFS311MD	M	200	2000
	LFS311LG	L	200	2000
	LFS311XL	XL	170	1700
HALYARD* **PURE**ZERO* LIMON-XTRA* Nitrile Exam Gloves - 12"/30.5cm Length	LFS321XS	XS	100	1000
	LFS321SM	S	100	1000
	LFS321MD	M	100	1000
	LFS321LG	L	100	1000
	LFS321XL	XL	100	1000

Storage Instructions

HALYARD* **PURE**ZERO* Nitrile Gloves shall be stored in conditions where the product is kept dry (away from moisture), away from direct sunlight, away from sources of heat, and away from radioactive sources.



Quality & Regulatory Standards

Compliant to these regulatory standards:
- ISO 9001:2015
- ISO 13485:2016
- 10993-10, 10993-11
- ISO 14001:2015

Comply with FDA 21 CFR part 820 / Meet FDA 21 CFR Part 820
Compliance to REGULATION (EU) 2017/745
Compliant to these food handling regulatory standards:
- FDA 21 CFR 177.2600
- FDA 21 CFR 180.22
- Commission Regulation (EU) No 10/2011

CE 2797 PPE Category III according to Regulation (EU) 2016/425
Comply with PPE Cat III according
- Regulation (EU) 2016/425 (CE 2797)
- Regulation (EU) 2016/425 as amended to apply in GB (UKCA 0086)

Compliant with the REACH regulation

US Standards
- ASTM F1671
- ASTM F739-12
- ASTM D6978-05
- ASTM D6319

EU MDR Standards
- EN 455-1:2020+A1:2022
- EN 455-2:2015
- EN 455-3:2015
- EN 455-4:2009

EU/UKCA PPE
- EN ISO 21420:2020
- EN ISO 374-1:2016+A1:2018
- EN ISO 374-2:2019
- EN ISO 374-4:2019
- EN ISO 374-5:2016 Virus Protection
- EN 16523-1:2015+A1:2018
- ISO-16604:2004

CE 2797 (PPE Cat. III)

UKCA 0086

ISO 374-5:2016 VIRUS

Applies only to 12" LIMON-XTRA* Nitrile Exam Gloves
EN ISO 374-1/Type B KTJ

Applies only to 9.5" LIMON* Nitrile Exam Gloves
EN ISO 374-1/Type C K-Low Chemical

For additional information or samples, contact your local distributor.

This fact sheet has been created using the most recent information. In the interest of continuous improvement, the characteristics of the products may change without prior notice.

Owens & Minor

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008389 COPY-05421 March 2025

September 16, 2022

RE: HALYARD* PUREZERO* Life Science Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding the chemotherapy drugs tested on **HALYARD* PUREZERO* Life Science Nitrile Gloves.**

The results below reflect a comprehensive list of chemotherapy and hazardous drugs tested on **HALYARD* PUREZERO* Life Science Nitrile Gloves** with indicated breakthrough time in accordance with ASTM D6978, *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*.

PUREZERO* MARIN* and MARIN-XTRA* Nitrile Gloves

Chemotherapy Drug and Concentration	Minimum Breakthrough Time (min.)
Carmustine (3.3 mg/ml)	Breakthrough detected at **55.2** minutes
Cisplatin (1 mg/ml)	No breakthrough up to 240 minutes
Cyclophasphamide (20 mg/ml)	No breakthrough up to 240 minutes
Dacarbazine (10 mg/ml)	No breakthrough up to 240 minutes
Doxorubicin HCL (2.0 mg/ml)	No breakthrough up to 240 minutes
Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
Methotrexate (25 mg/ml)	No breakthrough up to 240 minutes
Mitomycin C (0.5 mg/ml)	No breakthrough up to 240 minutes
Mitoxantrone HCl (2 mg/ml)	No breakthrough up to 240 minutes
Paclitaxel (6.0 mg.ml)	No breakthrough up to 240 minutes
Thiotepa (10.0 mg/ml)	Breakthrough detected at **88.6** minutes
Vincristine (1 mg/ml)	No breakthrough up to 240 minutes
Fentanyl Citrate Injection (100 mcg/2mL)	No breakthrough up to 240 minutes
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution	No breakthrough up to 240 minutes

PUREZERO* LIMON* and LIMON-XTRA* Nitrile Gloves

Chemotherapy Drug and Concentration	Minimum Breakthrough Time (min.)
Carmustine (3.3 mg/ml)	Breakthrough detected at **34.3** minutes
Cisplatin (1 mg/ml)	No breakthrough up to 240 minutes
Cyclophasphamide (20 mg/ml)	No breakthrough up to 240 minutes
Dacarbazine (10 mg/ml)	No breakthrough up to 240 minutes
Doxorubicin HCL (2.0 mg/ml)	No breakthrough up to 240 minutes
Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
Methotrexate (25 mg/ml)	No breakthrough up to 240 minutes
Mitomycin C (0.5 mg/ml)	No breakthrough up to 240 minutes
Mitoxantrone HCl (2 mg/ml)	No breakthrough up to 240 minutes
Paclitaxel (6.0 mg.ml)	No breakthrough up to 240 minutes
Thiotepa (10.0 mg/ml)	Breakthrough detected at **87.6** minutes
Vincristine (1 mg/ml)	No breakthrough up to 240 minutes
Fentanyl Citrate Injection (100 mcg/2mL)	No breakthrough up to 240 minutes
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution	No breakthrough up to 240 minutes

PUREZERO* ULTRA VIOLET* Nitrile Gloves

Chemotherapy Drug and Concentration	Minimum Breakthrough Time (min.)
Carmustine (3.3 mg/ml)	Breakthrough detected at **16.2** minutes
Cisplatin (1 mg/ml)	No breakthrough up to 240 minutes
Cyclophasphamide (20 mg/ml)	No breakthrough up to 240 minutes
Dacarbazine (10 mg/ml)	No breakthrough up to 240 minutes
Doxorubicin HCL (2.0 mg/ml)	No breakthrough up to 240 minutes
Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
Methotrexate (25 mg/ml)	No breakthrough up to 240 minutes
Mitomycin C (0.5 mg/ml)	No breakthrough up to 240 minutes
Mitoxantrone HCl (2 mg/ml)	No breakthrough up to 240 minutes
Paclitaxel (6.0 mg.ml)	No breakthrough up to 240 minutes
Thiotepa (10.0 mg/ml)	Breakthrough detected at **28.4** minutes
Vincristine (1 mg/ml)	No breakthrough up to 240 minutes

CAUTION: The testing conditions used are intended to approximate the worst-case conditions for clinical use. Testing was conducted on a single layer glove material. It is the user's responsibility to demonstrate the applicability of these gloves for their intended use with chemotherapy drugs.

Sincerely,

Shannon Smith

Shannon Smith
Associate Product Manager
Products & Healthcare Services
O&M Halyard, Inc.

Ryan Solan

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

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COPY-04429

September 16, 2022

RE: HALYARD* PUREZERO* Life Science Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding chemical permeation testing for the HALYARD* PUREZERO* Life Science Nitrile Gloves, which include: MARIN*, MARIN-XTRA*, LIMON*, LIMON-XTRA* and ULTRA VIOLET.

The results below reflect a comphrensive list of chemicals tested against HALYARD* PUREZERO* Life Science Nitrile Gloves with indicated breakthrough time in accordance with ASTM F739: *Standard Test Method for Permeation of Liquid and Gases Through Protective Chlothing Materials Under Conditions of Continuous Contact.*

PUREZERO* MARIN* and MARIN-XTRA* Nitrile Gloves

Chemical	Concentration (%)	Average Breakthrough Time (min.)
n-Amyl, Acetate	100	**0**
Acetic Acid (Glacial)	-	**10.0**
Acrylamide	40	**243.3**
Ammonium Hydroxide	30	**0**
Carbon Disulfide	99.9	**0**
Carbon Tetrachloride	99.9	**8.0**
CaviCide	-	No breakthrough detected up to **480** minutes
Chlorhexidine Digluconate	4	No breakthrough detected up to **480** minutes
Cidex OPA	-	**173.3**
Citric Acid	10	No breakthrough detected up to **480** minutes
Citric Acid	50	No breakthrough detected up to **480** minutes
Cyclohexane, ACS Reagent	99	**45.3**
Cyclohexanol	99	No breakthrough detected up to **480** minutes
Denatured Ethanol	92	**8.0**
Dibutyl Phthalate	99	**80.0**
Diisobutyl Ketone	90	**8.0**
Dimethyl Sulfoxide	-	**10.0**
Ethidium Bromide	10	No breakthrough detected up to **480** minutes
Ethyl Alcohol	99	**16.0**
Ethylene Glycol	99	No breakthrough detected up to **480** minutes
Formaldehyde	37	No breakthrough detected up to **480** minutes
Formalin (Tested for Formaldehyde)	-	No breakthrough detected up to **480** minutes

Formalin (Tested for Methanol)	-	No breakthrough detected up to **480** minutes
Glutaraldehyde	25	No breakthrough detected up to **480** minutes
Glutaraldehyde	50	No breakthrough detected up to **480** minutes
Hydrazine	65	**140.0**
Hydrazine	98	**136.7**
Hydrochloric Acid	10	No breakthrough detected up to **480** minutes
Hydrochloric Acid	37	**286.7**
Hydrogen Peroxide	3	No breakthrough detected up to **480** minutes
Hydrogen Peroxide	30	**60.0**
Instra-Clean Single Enzyme Solution	-	No breakthrough detected up to **480** minutes
Isopropyl Alcohol	70	**41.0**
Isopropyl Alcohol	99	**41.0**
MetriCide 14 Day Cleaner	-	No breakthrough detected up to **480** minutes
n-Hexane	96	**40.0**
Nitric Acid	10	No breakthrough detected up to **480** minutes
Nitric Acid	70	**5.0**
n-Octyl Alcohol, ACS Reagent	99	No breakthrough detected up to **480** minutes
Oleic Acid	90	No breakthrough detected up to **480** minutes
Oxycide Concentrated	-	**31.7**
Oxycide RTU	-	No breakthrough detected up to **480** minutes
Phosphoric Acid	85	No breakthrough detected up to **480** minutes
Potassium Hydroxide	50	No breakthrough detected up to **480** minutes
Povidone Iodine	10	No breakthrough detected up to **480** minutes
n-Propyl Alcohol HPLC Grade	-	**29.3**
Propylene Glycol	100	No breakthrough detected up to **480** minutes
Propylene Glycol Methyl Ether Acetate	-	**0**
Quaternary Cleaners	-	No breakthrough detected up to **480** minutes
Sodium Hydroxide	50	No breakthrough detected up to **480** minutes
Sodium Hypochlorite	10-13	No breakthrough detected up to **480** minutes
Stoddard Solvent	-	**95.0**
Sulfuric Acid	50	No breakthrough detected up to **480** minutes
Triethanolamine	99	No breakthrough detected up to **480** minutes
Turpentine	-	**77.0**
O-Xylene, Reagent Grade	98	**0**
Xylenes Mixed (Xylol)	-	**0**

PUREZERO* LIMON* and LIMON-XTRA* Nitrile Gloves

Chemical	Concentration (%)	Average Breakthrough Time (min.)
n-Amyl, Acetate	100	**0**
Acetic Acid (Glacial)	-	**10.0**
Acrylamide	40	**120.0**
Ammonium Hydroxide	30	**10.0**
Carbon Disulfide	99.9	**0**
Carbon Tetrachloride	99.9	**0**
CaviCide	-	No breakthrough detected up to **480** minutes
Chlorhexidine Digluconate	4	No breakthrough detected up to **480** minutes
Cidex OPA	-	**66.7**
Citric Acid	10	No breakthrough detected up to **480** minutes
Citric Acid	50	No breakthrough detected up to **480** minutes
Cyclohexane, ACS Reagent	99	**32.0**
Cyclohexanol	99	**128.0**
Denatured Ethanol	92	**9.0**
Dibutyl Phthalate	99	**53.3**
Diisobutyl Ketone	90	**0**
Dimethyl Sulfoxide	-	**5.0**
Ethidium Bromide	10	No breakthrough detected up to **480** minutes
Ethyl Alcohol	99	**8.0**
Ethylene Glycol	99	No breakthrough detected up to **480** minutes
Formaldehyde	37	No breakthrough detected up to **480** minutes
Formalin (Tested for Formaldehyde)	-	No breakthrough detected up to **480** minutes
Formalin (Tested for Methanol)	-	No breakthrough detected up to **480** minutes
Glutaraldehyde	25	No breakthrough detected up to **480** minutes
Glutaraldehyde	50	No breakthrough detected up to **480** minutes
Hydrazine	65	**86.7**
Hydrazine	98	**46.7**
Hydrochloric Acid	10	No breakthrough detected up to **480** minutes
Hydrochloric Acid	37	**113.3**
Hydrogen Peroxide	3	No breakthrough detected up to **480** minutes
Hydrogen Peroxide	30	**23.3**
Instra-Clean Single Enzyme Solution	-	No breakthrough detected up to **480** minutes
Isopropyl Alcohol	70	**24.0**
Isopropyl Alcohol	99	**24.0**
MetriCide 14 Day Cleaner	-	No breakthrough detected up to **480** minutes

n-Hexane	96	**8.0**
Nitric Acid	10	No breakthrough detected up to **480** minutes
Nitric Acid	70	**0**
n-Octyl Alcohol, ACS Reagent	99	No breakthrough detected up to **480** minutes
Oleic Acid	90	No breakthrough detected up to **480** minutes
Oxycide Concentrated	-	**15.0**
Oxycide RTU	-	No breakthrough detected up to **480** minutes
Phosphoric Acid	85	No breakthrough detected up to **480** minutes
Potassium Hydroxide	50	No breakthrough detected up to **480** minutes
Povidone Iodine	10	No breakthrough detected up to **480** minutes
n-Propyl Alcohol HPLC Grade	-	**16.0**
Propylene Glycol	100	No breakthrough detected up to **480** minutes
Propylene Glycol Methyl Ether Acetate	-	**5.0**
Quaternary Cleaners	-	No breakthrough detected up to **480** minutes
Sodium Hydroxide	50	No breakthrough detected up to **480** minutes
Sodium Hypochlorite	10-13	No breakthrough detected up to **480** minutes
Stoddard Solvent	-	**34.7**
Sulfuric Acid	50	No breakthrough detected up to **480** minutes
Triethanolamine	99	No breakthrough detected up to **480** minutes
Turpentine	-	**24.0**
O-Xylene, Reagent Grade	98	**0**
Xylenes Mixed (Xylol)	-	**0**

PUREZERO* ULTRA VIOLET* Nitrile Gloves

Chemical	Concentration (%)	Average Breakthrough Time (min.)
n-Amyl, Acetate	100	**0**
Acetic Acid (Glacial)	-	**0**
Acrylamide	40	**66.7**
Ammonium Hydroxide	30	**23.3**
Carbon Disulfide	99.9	**0**
Carbon Tetrachloride	99.9	**0**
CaviCide	-	**86.7**
Chlorhexidine Digluconate	4	No breakthrough detected up to **480** minutes
Cidex OPA	-	**86.7**
Citric Acid	10	No breakthrough detected up to **480** minutes
Citric Acid	50	No breakthrough detected up to **480** minutes

Cyclohexane, ACS Reagent	99	**50.7**
Cyclohexanol	99	No breakthrough detected up to **480** minutes
Denatured Ethanol	92	**0**
Dibutyl Phthalate	99	**40.0**
Diisobutyl Ketone	90	**8.0**
Dimethyl Sulfoxide	-	**0**
Ethidium Bromide	10	No breakthrough detected up to **480** minutes
Ethyl Alcohol	99	**8.0**
Ethylene Glycol	99	No breakthrough detected up to **480** minutes
Formaldehyde	37	**140.0**
Formalin (Tested for Formaldehyde)	-	No breakthrough detected up to **480** minutes
Formalin (Tested for Methanol)	-	No breakthrough detected up to **480** minutes
Glutaraldehyde	25	No breakthrough detected up to **480** minutes
Glutaraldehyde	50	**246.7**
Hydrazine	65	**96.7**
Hydrazine	98	**30.0**
Hydrochloric Acid	10	No breakthrough detected up to **480** minutes
Hydrochloric Acid	37	**80.0**
Hydrogen Peroxide	3	No breakthrough detected up to **480** minutes
Hydrogen Peroxide	30	**10.0**
Instra-Clean Single Enzyme Solution	-	No breakthrough detected up to **480** minutes
Isopropyl Alcohol	70	**8.0**
Isopropyl Alcohol	99	**16.0**
MetriCide 14 Day Cleaner	-	No breakthrough detected up to **480** minutes
n-Hexane	96	**16.0**
Nitric Acid	10	No breakthrough detected up to **480** minutes
Nitric Acid	70	**0**
n-Octyl Alcohol, ACS Reagent	99	No breakthrough detected up to **480** minutes
Oleic Acid	90	No breakthrough detected up to **480** minutes
Oxycide Concentrated	-	**10.0**
Oxycide RTU		No breakthrough detected up to **480** minutes
Phosphoric Acid	85	No breakthrough detected up to **480** minutes
Potassium Hydroxide	50	No breakthrough detected up to **480** minutes
Povidone Iodine	10	No breakthrough detected up to **480** minutes
n-Propyl Alcohol HPLC Grade	-	**8.0**
Propylene Glycol	100	No breakthrough detected up to **480** minutes
Propylene Glycol Methyl Ether Acetate	-	**0**

Quaternary Cleaners	-	No breakthrough detected up to **480** minutes
Sodium Hydroxide	50	No breakthrough detected up to **480** minutes
Sodium Hypochlorite	10-13	No breakthrough detected up to **480** minutes
Stoddard Solvent	-	**8.0**
Sulfuric Acid	50	No breakthrough detected up to **480** minutes
Triethanolamine	99	No breakthrough detected up to **480** minutes
Turpentine	-	**37.3**
O-Xylene, Reagent Grade	98	**0**
Xylenes Mixed (Xylol)	-	**0**

Sincerely,

Shannon Smith

Shannon Smith
Associate Product Manager
Products & Healthcare Services
O&M Halyard, Inc.

Ryan Solan

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

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COPY-04416

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Name of Product:	Synthetic Gloves – Non-sterile
Product Codes:	See **Attachment A**
Technical File Number :	012-04 Rev.02
UMDNS Code:	N/A
GMDN Code:	56286 (Nitrile examination/treatment glove, non-powdered, non-sterile)
CND Code:	T01020204: Examination / Treatment Gloves, Nitrile
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
Manufacturer SRN :	N/A
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN:	IE-AR-000003110
Basic UDI-DI:	06806517MEG001A3
Start of CE:	28 October 2022 per Regulation 2017/745 21 September 2022 per Regulation 2016/425
Conformity Assessment Route:	Annex VIII of Regulation (EU) 2017/745 **MDR 2017/745** It concerns a self-certified medical device in accordance with the MDR and that the DoC was drawn up in accordance with annex IV and the technical documentation in accordance with annex II and III. **PPER 2016/425** The PPE are subject to the conformity assessment procedure conformity to type based on quality assurance of the production process' (Module B) set out in Annex V under surveillance of the

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information

	notifed body BSI Group Netherland, Notified Body Number 2797 (John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands), which issued the certificate CE 759289, CE 759290, CE 759291, CE 760576 and CE 760577.
Risk Classification, Rules:	Class I NS per Rule 4, Annex VIII Regulation (EU) 2017/745 Category III PPE per Regulation (EU) 2016/425
Notified Body:	BSI Group Netherlands Notified Body Number 2797 John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Quality System Certificate:	FM 697013

COMMON SPECIFICATIONS: **NOT APPLICABLE**

The object of the declaration is in conformity with the PPE Regulation 2016/425, in addition to Medical Device Regulation (EU) 2017/745. Conformity is declared with the following standards:

Applicable Standards:	
Quality System	BS EN ISO 13485:2016 PPE Regulation (EU) 2016/425 (MODULE C2)
Risk Management	BS EN ISO 14971:2019
Biocompatibility	BS EN ISO 10993-2009 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013
Packaging	(Not Applicable)
Labeling	BS EN ISO 15223-1:2015 and BS EN 1041:2008+A1:2013
Sterilization	(Not Applicable) Non-Sterile
Clinical	MEDDEV 2.7.1
Product Specific	EN 455-1:2020* EN 455-2:2015* EN 455-3:2015* EN 455-4:2009* EN ISO 21420:2020 EN ISO 374-1:2016+A1:2018 EN ISO 374-2:2019 EN ISO 374-4:2019 EN ISO 374-5:2016 EN 16523-1:2015+A1:2018 ISO 16604:2004

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information

STATEMENT: I, the undersigned, hereby declare that the product listed in Attachment A meets the applicable provisions of the Regulation (EU) 2017/745 concerning Medical Devices and Regulation (EU) 2016/425 concerning Personal Protective Equipment.

All supporting documentation that contains proof of compliance to the aforementioned Regulation(s) is retained under the premises of O&M Halyard, Inc.

Authorized Signature:

On behalf of O&M Halyard, Inc

Angela L. Bunn

Name: Angela L. Bunn
Title: Sr. Director, Global Regulatory Affairs
Address: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
United States of America
Date: 28-October-2022

ATTACHMENT A: Product List

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information

Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity.

Alternative Code	Product Code	Product Description	Start of CE mark
LFS111XS	48761	PUREZERO* MARIN* NITRILE Exam Gloves/X-Small (5,5)	28 October 2022
LFS111SM	48762	PUREZERO* MARIN* NITRILE Exam Gloves/Small (6,5)	28 October 2022
LFS111MD	48763	PUREZERO* MARIN* NITRILE Exam Gloves/Medium (7,5)	28 October 2022
LFS111LG	48764	PUREZERO* MARIN* NITRILE Exam Gloves/Large (8,5)	28 October 2022
LFS111XL	48765	PUREZERO* MARIN* NITRILE Exam Gloves/X-Large (9,0)	28 October 2022
LFS121XS	48766	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves X-Small (5,5)	28 October 2022
LFS121SM	48767	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves /Small (6,5)	28 October 2022
LFS121MD	48768	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves/Medium (7,5)	28 October 2022
LFS121LG	48769	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves /Large (8,5)	28 October 2022
LFS121XL	48770	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves /X-Large (9,0)	28 October 2022
LFS311XS	48745	PUREZERO* Limon* NITRILE Exam Gloves/X-Small (5,5)	28 October 2022
LFS311SM	48746	PUREZERO* Limon* NITRILE Exam Gloves/Small (6,5)	28 October 2022
LFS311MD	48747	PUREZERO* Limon* NITRILE Exam Gloves/Medium (7,5)	28 October 2022
LFS311LG	48748	PUREZERO* Limon* NITRILE Exam Gloves/Large (8,5)	28 October 2022
LFS311XL	48749	PUREZERO* Limon* NITRILE Exam Gloves/X-Large (9,0)	28 October 2022
LFS321XS	48750	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/X-Small (5,5)	28 October 2022
LFS321SM	48751	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/Small (6,5)	28 October 2022
LFS321MD	48752	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/Medium (7,5)	28 October 2022
LFS321LG	48753	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/Large (8,5)	28 October 2022
LFS321XL	48754	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/X-Large (9,0)	28 October 2022
LFS511XS	48771	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/X-Small (5,5)	28 October 2022
LFS511SM	48772	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/Small (6,5)	28 October 2022
LFS511MD	48773	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/Medium (7,5)	28 October 2022
LFS511LG	48774	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/Large (8,5)	28 October 2022
LFS511XL	48775	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/X-Large (9,0)	28 October 2022

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information

EU Type Examination Certificate

This is to certify that:

O&M Halyard Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate Number: CE 759289

In respect of:

Nitrile Gloves for Personal Protection
Model: Halyard Purezero* Limon* Exam Gloves.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

First Issued: 2022-09-21
Latest Issue: 2022-10-24

Effective Date: 2022-10-24
Expiry Date: 2027-09-21

PRODUCTS
RvA C 646

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 759289

Product Specification

Range:	Halyard Purezero* Limon* Nitrile Exam Gloves
Models:	**LFS311XS** **LFS311SM** **LFS311MD** **LFS311LG** **LFS311XL**
Classification:	Protective gloves for use against chemical and micro-organism hazards.
Description:	A five fingered, ambidextrous, single-use, powder-free, nitrile glove with textured finger surfaces and length of 240mm (9.5inch).
Colour:	Green
Product codes:	48745, 48746, 48747, 48748, 48749
PPE Category:	Complex
Product sizes:	6 (XS), 7 (S), 8 (M), 9 (L), 10 (XL)
Technical Specifications:	Type Examination for all PPE models listed in the certificate is conducted to Annex II of the PPE Regulation (EU) 2016/425 and based on the following European Standards: EN ISO 21420:2020 Protective gloves. General requirements. EN ISO 374-1:2016+A1:2018. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks. EN ISO 374-2:2019. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration. (Test Method) EN ISO 374-4:2019 Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method) EN ISO 374-5:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks. EN 16523-1:2015+A1:2018. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact. (Test Method) BS ISO 16604:2004 Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by blood-borne pathogens. (Test Method)

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Performance:

General requirements for gloves to EN ISO 21420:2020

Characteristic	Result
pH	Pass
PAH	Pass
Dexterity	Level 5

Resistance to penetration to EN ISO 374-2:2019
Pass

Resistance to degradation to EN ISO 374-4:2019
Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018
Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
Sodium Hydroxide 40% (K)	6
Formaldehyde 37% (T)	6
n-Heptane (J)	2

Additional chemicals tested to EN 16523-1:2015+A1:2018 method:

Chemical	Level
Ethidium Bromide 1%	6
Hydrochloric Acid 30%	4
Sulphuric Acid 50%	6
70% Isopropanol	2

Protection against micro-organism risks to EN ISO 374-5:2016

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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EU Type Examination Certificate

No. CE 759289

Certificate Administration Details

Technical File Reference: Technical File Number: 012-04.

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
September 2022	First issue under PPE Regulation (EU) 2016/425.	2797:22:3555367
October 2022	Addition of two new chemicals, change to Type B chemical protection.	2797:22:3754596

Note: The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE:
The validity of the Certificate for the products is also dependent on the maintenance of the Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 708082.

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