

Halyard



## Empfohlene Reinraumklassen

ISO 7|8|9

GMP C|D



## Halyard Nitril-Handschuhe PUREZERO LIMON- XTRA #LFS321LG

pure<sup>11</sup>-Nr.: 1105352, Marke: Halyard

### Eigenschaften

- Marke: Halyard
- Handschuhtyp: Dünnsfilm
- Länge in cm: 30 cm
- Chemikalienbeständigkeit - Typ: Typ B
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Zytostatikageeignet
- Lebensmittelkonformität
- Verpackungsform: Spenderbox
- AQL (Acceptable Quality Level)-Wert: 1
- Länge in Inches: 11,8 In
- Latexfrei
- Passform Hand: beidhändig
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,12 mm

## Material

- Nitril

## Verpackung

- 1000STK

## Produktvarianten

---

**pure<sup>11</sup>-Nr.: 1105352GNL, Halyard Nitril-Handschuhe PUREZERO LIMON-XTRA #LFS321LG**

Farbe: Grün; Größe: L / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1105352GNM, Halyard Nitril-Handschuhe PUREZERO LIMON-XTRA #LFS321MD**

Farbe: Grün; Größe: M / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1105352GNS, Halyard Nitril-Handschuhe PUREZERO LIMON-XTRA #LFS321SM**

Farbe: Grün; Größe: S / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1105352GNXL, Halyard Nitril-Handschuhe PUREZERO LIMON-XTRA #LFS321XL**

Farbe: Grün; Größe: XL / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1105352GNXS, Halyard Nitril-Handschuhe PUREZERO LIMON-XTRA #LFS321XS**

Farbe: Grün; Größe: XS / VE: 1000STK

---

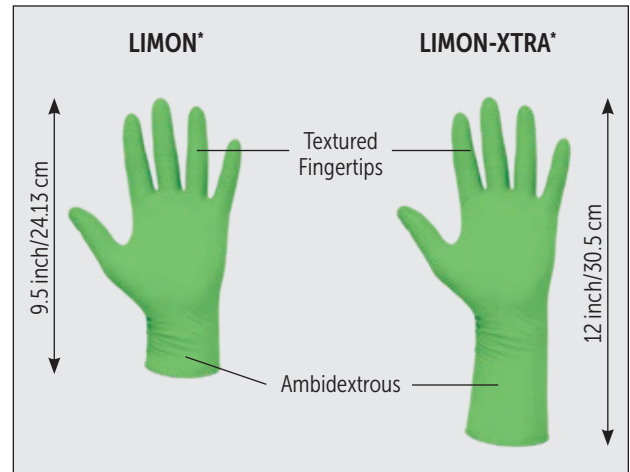


# HALYARD\* PUREZERO\* LIMON\* and LIMON-XTRA\* Nitrile Exam Gloves For Medical/Industrial/Lab Use

## TECHNICAL DATA SHEET

### Description

HALYARD\* **PUREZERO\*** 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\* **PUREZERO\*** LIMON\* and LIMON-XTRA\* Nitrile Exam Gloves are tested for use against 57 chemicals and 14 chemotherapy drugs. The beaded cuff allows for ease of donning, and textured fingertips provide tactile agility.



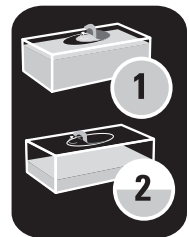
Manufactured at  
**OUR OWN** Safeskin  
Facility in Thailand.

### Physical Properties

|                                    |                 |
|------------------------------------|-----------------|
| AQL                                | 1.0             |
| Non-Sterile                        | ✓               |
| Ambidextrous                       | ✓               |
| Textured Fingertips                | ✓               |
| Not Made With Natural Rubber Latex | ✓               |
| Powder-Free                        | ✓               |
| Tensile Strength <sup>1</sup>      | 38 MPa (Target) |
| Ultimate Elongation <sup>1</sup>   | 550%            |
| 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\* PUREZERO\* 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* PUREZERO* 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* PUREZERO* 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      |

### Quality & Regulatory Standards

Compliant to these regulatory standards:

ISO 9001  
ISO 13485:2016  
ISO 10993

Compliance to REGULATION (EU) 2017/745

Compliant to these food handling regulatory standards:

FDA 21 CFR 177-2600  
Commission Regulation (EU) No 10/2011

FDA 21 CFR part 820 accreditation

CE 2797 PPE Category III according to Regulation (EU) 2016/425 EEC

EN ISO 374-5:2016 Virus Protection  
EN ISO 374-1:2016/Type B Chemical Protection

Compliant with the REACH regulation

#### US Standards

ASTM F1671  
ASTM F739-12  
ASTM D6978-05

#### EU MDR Standards

EN 455-1:2020  
EN 455-2:2015  
EN 455-3:2015  
EN 455-4:2009

#### EU PPE

EN ISO 21420:2020  
EN ISO 374-1:2016+A1:2018  
EN ISO 374-2:2019  
EN 16523-1:2015+A1:2018  
EN ISO 374-4:2019  
ISO-16604:2004

Meets  
USP <800>  
Guidelines.



CE 2797  
(PPE Cat. III)

ISO 374-5:2016  
VIRUS

UK  
CA  
0086

EN ISO 374-1:2016  
Type B



For additional information  
or samples, contact your  
local distributor.

1 Tested per ASTM D6319, EN 455-2

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.



# HALYARD\* PUREZERO\* LIMON\* and LIMON-XTRA\* Nitrile Exam Gloves For Medical/Industrial/Lab Use

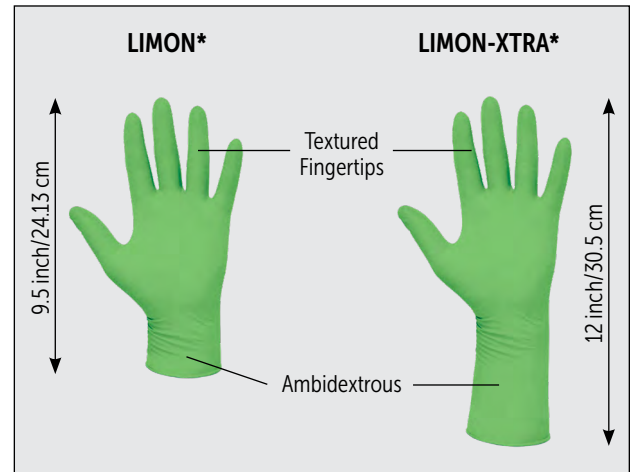
## TECHNICAL DATA SHEET

Tested  
against  
Fentanyl &  
Xylazine.

Meets  
USP <800>  
Guidelines.

### Description

HALYARD\* **PUREZERO\*** 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\* **PUREZERO\*** 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.



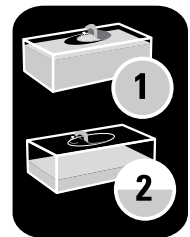
Manufactured at  
**OUR OWN** Safeskin  
Facility in Thailand.

### Physical Properties

|                                    |                 |
|------------------------------------|-----------------|
| AQL                                | 1.0             |
| Non-Sterile                        | ✓               |
| Ambidextrous                       | ✓               |
| Textured Fingertips                | ✓               |
| Not Made With Natural Rubber Latex | ✓               |
| Powder-Free                        | ✓               |
| Tensile Strength <sup>1</sup>      | 42 MPa (Target) |
| Ultimate Elongation <sup>1</sup>   | 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\* PUREZERO\* 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* PUREZERO* 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* PUREZERO* 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\* PUREZERO\* 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)

UK  
CA  
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.



HALYARD\* is an Owens & Minor brand



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 <b>55.2</b> minutes |
| Cisplatin (1 mg/ml)                                                        | No breakthrough up to 240 minutes            |
| Cyclophosphamide (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 <b>88.6</b> 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 <b>34.3</b> minutes |
| Cisplatin (1 mg/ml)                                                        | No breakthrough up to 240 minutes            |
| Cyclophosphamide (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 <b>87.6</b> 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 <b>16.2</b> minutes |
| Cisplatin (1 mg/ml)                 | No breakthrough up to 240 minutes            |
| Cyclophosphamide (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 <b>28.4</b> 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.

\*Registered Trademark or Trademark of O&M Halyard or its affiliates. ©2021. All rights reserved.

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

## 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 <b>480</b> minutes |
| Chlorhexidine Digluconate          | 4                 | No breakthrough detected up to <b>480</b> minutes |
| Cidex OPA                          | -                 | 66.7                                              |
| Citric Acid                        | 10                | No breakthrough detected up to <b>480</b> minutes |
| Citric Acid                        | 50                | No breakthrough detected up to <b>480</b> 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 <b>480</b> minutes |
| Ethyl Alcohol                      | 99                | 8.0                                               |
| Ethylene Glycol                    | 99                | No breakthrough detected up to <b>480</b> minutes |
| Formaldehyde                       | 37                | No breakthrough detected up to <b>480</b> minutes |
| Formalin (Tested for Formaldehyde) | -                 | No breakthrough detected up to <b>480</b> minutes |
| Formalin (Tested for Methanol)     | -                 | No breakthrough detected up to <b>480</b> minutes |
| Glutaraldehyde                     | 25                | No breakthrough detected up to <b>480</b> minutes |
| Glutaraldehyde                     | 50                | No breakthrough detected up to <b>480</b> minutes |
| Hydrazine                          | 65                | 86.7                                              |
| Hydrazine                          | 98                | 46.7                                              |
| Hydrochloric Acid                  | 10                | No breakthrough detected up to <b>480</b> minutes |
| Hydrochloric Acid                  | 37                | 113.3                                             |
| Hydrogen Peroxide                  | 3                 | No breakthrough detected up to <b>480</b> minutes |
| Hydrogen Peroxide                  | 30                | 23.3                                              |
| Insta-Clean Single Enzyme Solution | -                 | No breakthrough detected up to <b>480</b> minutes |
| Isopropyl Alcohol                  | 70                | 24.0                                              |
| Isopropyl Alcohol                  | 99                | 24.0                                              |
| MetriCide 14 Day Cleaner           | -                 | No breakthrough detected up to <b>480</b> minutes |

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

## PUREZERO\* ULTRA VIOLET\* Nitrile Gloves

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

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

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

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.

\*Registered Trademark or Trademark of O&M Halyard or its affiliates. ©2021. All rights reserved.

COPY-04416

## EC Declaration of Conformity

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

|                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name of Product:</b>                     | Synthetic Gloves – Non-sterile                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Product Codes:</b>                       | See <b>Attachment A</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Technical File Number :</b>              | 012-04 Rev.02                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>UMDNS Code:</b>                          | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>GMDN Code:</b>                           | 56286 (Nitrile examination/treatment glove, non-powdered, non-sterile)                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>CND Code:</b>                            | T01020204: Examination / Treatment Gloves, Nitrile                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Legal Manufacturer (Place of Issue):</b> | O&M Halyard, Inc.<br>9120 Lockwood Blvd.<br>Mechanicsville, Virginia (VA) 23116<br>United States of America                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Manufacturer SRN :</b>                   | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Authorized Representative:</b>           | ArcRoyal<br>Virginia Road Kells, Co<br>Meath, Ireland                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>AR SRN:</b>                              | IE-AR-000003110                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Basic UDI-DI:</b>                        | 06806517MEG001A3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Start of CE:</b>                         | 28 October 2022 per Regulation 2017/745<br>21 September 2022 per Regulation 2016/425                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Conformity Assessment Route:</b>         | <p>Annex VIII of Regulation (EU) 2017/745</p> <p><b>MDR 2017/745</b></p> <p>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.</p> <p><b>PPER 2016/425</b></p> <p>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</p> |

|                                    |                                                                                                                                                                                                                  |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    | notified body BSI Group Nederland, 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. |
| <b>Risk Classification, Rules:</b> | Class I NS per Rule 4, Annex VIII Regulation (EU) 2017/745<br>Category III PPE per Regulation (EU) 2016/425                                                                                                      |
| <b>Notified Body:</b>              | BSI Group Netherlands<br>Notified Body Number 2797<br>John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands                                                                                                  |
| <b>Quality System Certificate:</b> | 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:

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

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**

### 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  |

# EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

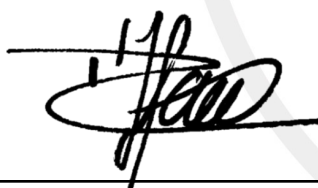
CE 760577

In respect of:

**Nitrile Gloves for Personal Protection**  
**Model: Halyard Purezero\* Limon-Xtra\* 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 Hagenaaers, Managing Director

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

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

Page: 1 of 4



# EU Type Examination Certificate

No. CE 760577

## Product Specification

**Range:** Halyard Purezero\* Limon-Xtra\* Nitrile Exam Gloves

**Models:** **LFS321XS** **LFS321LG**  
**LFS321SM** **LFS321XL**  
**LFS321MD**

**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 extended cuff length of 300mm (12inch).

**Colour:** Green

**Product codes:** 48750, 48751, 48752, 48753, 48754

**PPE Category:** Complex

**Product sizes:** 6 (XS), 7 (S), 8 (M), 9 (L), 10 (XL)

**Technical** 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:

### Specifications:

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)

First Issued: 2022-09-21

Latest Issue: 2022-10-24

Effective Date: 2022-10-24

Expiry Date: 2027-09-21

Page: 2 of 4

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 760577

## 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 |

First Issued: 2022-09-21

Latest Issue: 2022-10-24

Effective Date: 2022-10-24

Expiry Date: 2027-09-21

Page: 3 of 4

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 760577

## 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                       | 2797:22:3564590             |
| October 2022   | Addition of two new chemicals, change to Type B chemical protection. | 2797:22:3754599             |

**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.

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

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

Page: 4 of 4

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.