

# EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

CE 725270

In respect of:

**Nitrile Protective Gloves for Personal Protection**  
**Model: CLN323280LG (Sterile)**

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 Hagenaaars, Managing Director

First Issued: 2020-11-02

Latest Issue: 2020-11-02

Effective Date: 2020-11-02

Expiry Date: 2025-11-02

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# EU Type Examination Certificate

No. CE 725270

## Product Specification

**Range:** HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK

**Models:** CLN323260  
CLN323265  
CLN323270  
CLN323275  
CLN323280  
CLN323285  
CLN323290  
CLN323210

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**Description:** A five fingered, hand specific, single use powder free, non-sterile, gamma irradiated glove with textured finger surface and beaded cuff. Gloves available coloured white.

**PPE Category:** Complex

**Product sizes:** 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0

**Applicable** The following Harmonized European Standards:

**Standards:** EN 420:2003+A1:2009 Protective gloves. General requirements.

EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN 374-2:2019. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

EN 374-4:2019 Determination of resistance to degradation by chemicals.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks.

EN 16523-1:2015. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

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.

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## Product Specification

### Performance

#### General requirements for gloves to EN 420:2003+A1:2009

| Characteristic | Level |
|----------------|-------|
| Dexterity      | 5     |

#### Terminology and performance requirements for micro-organism Risks EN ISO 374-5:2016

| Characteristic                        | Level |
|---------------------------------------|-------|
| Protection against bacteria and fungi | Pass  |
| Protection against viruses            | Pass  |

#### Resistance to chemical permeation to EN ISO 374-1:2016

Tested to the chemicals below to EN 16523-1:2015

#### Resistance to Degradation to chemical protection EN 374-4:2019

Tested to the chemicals below

| Chemical                 | Permeation Level | Mean Degradation % |
|--------------------------|------------------|--------------------|
| 70% Isopropyl Alcohol    | -                | 61.2               |
| 40% Sodium Hydroxide (K) | 6                | -2.1               |
| 50% Sulphuric Acid       | 6                | -19.8              |
| 30% Hydrochloric Acid    | 6                | 74.9               |
| 1% Ethidium Bromide      | 6                | 16.4               |

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## Certificate Administration Details

Technical File Reference: No. 012-03 R01 Halyard Sterile Cleanroom Gloves

## Certificate Amendment Record:

| Issue Date    | Comments  | Internal BSI Project Number |
|---------------|---|-----------------------------|
| November 2020 | First issue models: CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323285, CLN323290, CLN323210. | 2797:20:3154544             |

**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 is also dependent on the maintenance of the EC quality of production by monitoring system, Module C2, as referenced on BSI Certificate CE 708082.

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