

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

CE 725275

In respect of:

**Nitrile Protective Gloves for Personal Protection.
Model CLN3231LG powder free 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 Hagenaaars, Managing Director

First Issued: 2020-11-17

Latest Issue: 2020-11-17

Effective Date: 2020-11-17

Expiry Date: 2025-11-17

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EU Type Examination Certificate

No. CE 725275

Product Specification

Range: Halyard Purezero HG3 Smooth White Nitrile Gloves Non-Sterile Ambi (SLICK)

Models: CLN3231XS
CLN3231SM
CLN3231MD
CLN3231LG
CLN3231XL

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

Description: A five fingered, ambidextrous, single use powder free, non-sterile, Nitrile with textured finger surface with smooth grip. Gloves are 310mm in length available coloured White.

PPE Category: Complex

Product sizes: XS, S, M, L, XL

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	-	70.5
40% Sodium Hydroxide (K)	6	-29.3
50% Sulphuric Acid	6	-37.9
30% Hydrochloric Acid	6	9.1
1% Ethidium Bromide	6	-9.8

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Certificate Administration Details

Technical File Reference: No. 012-02 R01 Halyard Non-Sterile Cleanroom Gloves Rev02.

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
November 2020	First issue models: CLN3231XS, CLN3231SM, CLN3231MD CLN3231LG, CLN3231XL.	2797:20:3154554

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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