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 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

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 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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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.

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