

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

CE 708079

In respect of:

Nitrile gloves for personal protection. Model: PURPLE NITRILE* MAX Powder Free 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):



Denelise L'Ecluse, Managing Director Assurance - Continental Europe

First Issued: 2019-03-14

Latest Issue: 2024-03-14

Effective Date: 2024-03-14

Expiry Date: 2029-03-14

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Product Specification

Model: PURPLE NITRILE* MAX

Classification: Protective gloves for use against microorganisms and general applications

Description: Nitrile rubber exam gloves, powder free, non-sterile, single use. Ambidextrous, textured glove with beaded cuff, available in purple colour. Glove length is 400mm.

Product codes: 47195 – Small
47196 – Medium
47197 – Large
47198 – X Large

Technical Specification

Technical Specification to Annex II of the PPE Regulation (EU) 2016/425, based on the following European Standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

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

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

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 using Phi-X174 Bacteriophage. (Test Method)

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Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 2

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
n-Heptane (J)	4
30% Hydrogen Peroxide (P)	5
37% Formaldehyde (T)	6

Additional chemicals tested to EN 16523-1:2015+A1:2016 method:

Chemical	Level
Ethidium Bromide 1%	6
Hydrochloric Acid 30%	6
Isopropyl Alcohol 70%	3
Isopropyl Alcohol 100%	3
Sulphuric Acid 50%	6
Ammonia 25%	2
Acetic Acid 99%	1

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

General requirements for gloves to EN ISO 21420:2020

Dexterity:	Level 5
pH:	Pass
PAH:	Pass
Size Range:	Small, Medium, Large and X Large

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Certificate Administration Details

Manufacturer's technical file reference: Technical File 012-01 Synthetic Gloves PPE.

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
March 2019	First issue under PPE Regulation (EU) 2016/425. Product previously certified to PPE Directive under CE 674552.	0086:19:9735321
March 2024	Amendment to include revised standard EN ISO 21420:2020; change of chemical protection claim to Type B; certificate 5 years expiry renewal.	2797:24:3640612

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process 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.

The validity of the Certificate for the products is also dependent on the maintenance of the EU 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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