

# EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

CE 708080

In respect of:

**Nitrile gloves for personal protection. Model: BASICS\* Blue Powder Free Nitrile Exam Gloves.**

on the basis BSI carried out the relevant Type Examination procedure in accordance with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment (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 0086):

  
Chris Lewis - Certification Director, Product Certification

First Issued: 2019-03-14  
Latest Issue: 2019-03-14

Effective Date: 2019-03-14  
Expiry Date: 2024-03-14

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# EU Type Examination Certificate

No. CE 708080

## Product Specification

**Model:** Basics\* Blue

**Classification:** Protective gloves for use against microorganisms and general applications

**Description:** Nitrile rubber exam gloves, powder free, non sterile with low chemical protection. Ambidextrous glove with beaded cuff and a smooth surface, available in blue colour.

**Product codes:** X Small – product code 44749  
Small – product code 44750  
Medium – product code 44751  
Large – product code 44752  
X Large – product code 44753

**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 microorganisms. Terminology and performance requirements for chemical risks.

EN 374-2:2014. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals.

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

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

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.

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.

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## Product Specification

**Performance:**      **Resistance to penetration to EN 374-2:2014**

Performance Level 2

**Resistance to degradation to EN 374-4:2013**

Tested for all chemicals listed below.

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

**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

Additional chemicals tested to EN 16523-1:2015 method:

<b>Chemical</b>	<b>Level</b>
Ethidium Bromide 1%	6
Hydrochloric Acid 30%	4
Sulphuric Acid 50%	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	X Small, 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 657763.	0086:19:9735322

## 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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