

# EU Type Examination Certificate

This is to certify that:

Mercator Medical S. A.  
Ul. H. Modrzejewskiej 30  
Cracow  
31-327  
Poland

Holds Certificate Number:

CE 698941

In respect of:

**Gloves for personal protection. Model: Nitrilex high risk - Powder Free Nitrile 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: 2018-10-30

Latest Issue: 2023-10-09

Effective Date: 2023-10-09

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Page: 1 of 5

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## Product Specification

<b>Model:</b>	<b>Nitrylex high risk - Powder Free Nitrile Gloves.</b>
<b>Classification:</b>	Protective gloves for use against dangerous chemical and micro-organism hazards.
<b>Description:</b>	A five fingered, ambidextrous, single use powder free, non-sterile, chlorinated Nitrile glove with textured finger surface and beaded cuff. Gloves available coloured blue or orange.
<b>PPE Category:</b>	Category III
<b>Size range:</b>	XS, S, M, L, XL, XXL, XXXL
<b>Applicable Standards:</b>	<p>The following standards:</p> <p>EN ISO 21420:2020 Protective gloves. General requirements and test methods. Incorporating Amendment 1 from ISO 21420:2020/Amd.1:2022</p> <p>EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.</p> <p>EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration.</p> <p>EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals</p> <p>EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks</p> <p>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.</p> <p>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.</p>

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Page: 2 of 5

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**Product Specification (continued)**

**Performance**

**General requirements for gloves to EN ISO 21420:2020 Incorporating Amendment 1 from ISO 21420:2020/Amd.1:2022**

Characteristic	Level
Dexterity	5
Size	XS, S, M, L, XL, XXL, XXXL
pH	Pass
PAH	Pass

**Terminology and performance requirements for micro-organism risks EN ISO 374-5:2016**

Characteristic	Level
Protection against bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Protection against viruses (Test Method ISO 16604:2004)	Pass

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Page: 3 of 5

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**Product Specification (continued)**

**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	Permeation Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	5
37% Formaldehyde (T)	6

**Resistance to Degradation to chemical protection EN ISO 374-4:2019**

Chemical	Mean Degradation %
40% Sodium Hydroxide (K)	-66.1
30% Hydrogen Peroxide (P)	26.9
37% Formaldehyde (T)	-9.0

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## Certificate Administration Details

Product initially approved on BSI certificate: CE 683251.

## Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
October 2018	First issue	0086:18:9642992
October 2023	Amendment to update the standards to the current revisions, remove the chemicals and Certificate renewal.	2797:23:3969813

**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 EU Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 688313.

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