

EU Type Examination Certificate

This is to certify that:

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

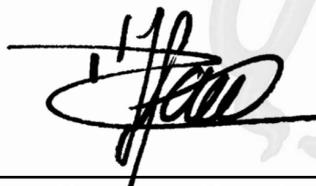
Holds Certificate Number:

CE 698941

In respect of:

**Disposable protective gloves to:
EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016, ISO
16604:2004, EN 16523-1:2015,
See continuation sheet for details.**

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):

Previous Notified Body: BSI 0086

First Issued: 2018-10-30

Latest Issue: 2019-09-12

Drs. Dave Hagenaaers, Managing Director

Effective Date: 2019-09-12

Expiry Date: 2023-10-30

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EU Type Examination Certificate

No. CE 698941

Product Specification

Model: Nitrylex high risk - Powder Free Nitrile Gloves.

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

Description: 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.

PPE Category: Complex

Product codes: XS, S, M, L, XL, and XXL

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

EN 374-4:2013 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 (continued)

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 permeation to chemical protection EN 16523-1:2015

Chemical	Permeation Level
40% Sodium Hydroxide	6
n-Heptane	1
50% Glutaraldehyde	6
5% Ethidium Bromide	6
70% Isopropanol	2
Toluene	0

Chemical	Permeation Level
1.5% methanol in water	6
0.1% Phenol	6
37% Formaldehyde	6
96% Sulphuric Acid	0
25% Ammonium Hydroxide	1
30% Hydrogen Peroxide	5

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Product Specification (continued)

Resistance to Degradation to chemical protection EN 374-4:2013

Chemical	Mean Degradation %	Chemical	Mean Degradation %
40% Sodium Hydroxide	-66.1	1.5% methanol in water	-20.3
n-Heptane	18.7	0.1% Phenol	-3.7
50% Glutaraldehyde	-42.5	37% Formaldehyde	-9.0
5% Ethidium Bromide	-33.8	96% Sulphuric Acid	100.0
70% Isopropanol	25.9	25% Ammonium Hydroxide	31.6
Toluene	62.2	30% Hydrogen Peroxide	26.9

Certificate Administration Details

Product initially approved on BSI certificate: CE 683251.

Certificate Amendment Record:

Issue Date	Comments
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October 2018	First issue
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Internal BSI Project Number

0086:18:9642992

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.

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Location

Kossan International Sdn Bhd
Wisma Kossan, Lot 782
Jalan Sungai Putus
Off Batu 3 3/4, Jalan Kapar
42100 Klang
Selangor
Malaysia

Certified Activities

Disposable protective gloves to:
EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014,
EN 374-4:2013, EN ISO 374-5:2016, ISO 16604:2004, EN
16523-1:2015,
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