

EU DECLARATION OF CONFORMITY

Manufacturer: **MERCATOR MEDICAL S.A.**
 UL. H.MODRZEJEWSKIEJ 30
 31-327 KRAKÓW, POLSKA

Declares under its sole responsibility that non-sterile examination and protective gloves:

Brand	Type	Sizes	Reference Numbers
nitrilex® classic	nitrile, powder-free, blue, for single use	XS (5-6) - XL (9-10)	a'100: RD30019001-05 a'200: RD30096001-05
	nitrile, powder-free, white, for single use	XS (5-6) - XL (9-10)	a'50: RD30174001-05 a'100: RD30143001-05 a'200: RD30097001-05
	nitrile, powder-free, violet, for single use	XS (5-6) - XL (9-10)	a'100: RD30169001-05 a'200: RD30168001-05
Basic UDI-DI: 5906615 RD NS N PF 9C			

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I according to Annex VIII of the Regulation (EU) 2017/745 and comply with European harmonized standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

The products described above are also classified as Personal Protective Equipment Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards: EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

The products described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. 2777/10015-03/E17-01 issued by notified body:

Satra Technology Europe Limited (2777)
 Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

and are subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:

Satra Technology Europe Limited (2777)
 Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Date and place of issue:
 05.05.2020, Kraków

Signed on the behalf of the Manufacturer:



Wojciech Hercka
 Product Documentation Manager

MERCATOR MEDICAL S.A.
 ul. Heleny Modrzejewskiej 30, 31-327 Kraków
 tel. 12 66 55 400, fax 12 66 55 415
 Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieście w Krakowie,
 XI Wydział Gospodarczy KRS, KRS: 0000036244
 Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
 NIP: 677-10-36-424, REGON: 350967107
 Numer BDO: 000056063
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EU Type-Examination Certificate

Certificate number: 2777/10015-03/E17-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product Reference

Nitrylex classic
Nitrylex one by one

Description

Disposable powder free nitrile glove available in white, blue and violet blue. Non-Sterile

Sizes: 5/6 (XS) to 9/10 (XL)

Classification:

EN ISO 374-1:2016 (Type B)

*4% Chlorhexidine Digluconate
40% Sodium Hydroxide (K)
10-13% Sodium Hypochlorite
50% Sulphuric Acid
10% Acetic Acid
5% Ethidium Bromide
37% Formaldehyde (T)
50% Glutaraldehyde
0.1% Phenol
30% Hydrogen Peroxide (P)
1.5% Methanol in water
25% Ammonium Hydroxide (O)
3% Povidone-iodine
10% Sodium Percarbonate
* Permeation rate 7µg/cm²/min

Level

6
6
6
6
4
6
3
6
6
2
6
6
6
6
1
6
6

EN374-4:2013 Degradation %

19.0
-42.9
14.7
-20.5
66.7
3.4
5.0
27.4
33.8
22.8
21.9
-52.0
33.7
15.4

EN ISO 374-5: 2016

Protection against Bacteria & Fungi
Protection against viruses

Pass
Pass

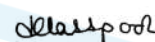
Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0216113/1327/SMcD/RS, SPC0216113/1327, PRC0250570/1640/SPT, CHM0248297/1630/EN/E, CHM0248297/1630/EN/D/Issue 2, CHM0257198/1719/SMcD/A, CHM0257198/1719/SMcD/B, CHM0257198/1719/SMcD/C, CHM0257198/1719/SMcD/D

Signed on behalf of SATRA:



Hannah Coe



Jacquie Glasspool

Date of issue: 18/09/2019

Expiry date: 21/04/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.