MERCATOR

# EU DECLARATION OF CONFORMITY

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

SRN: PL-MF-000018942

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

| Brand | Type | Packaging | Sizes | Reference Numbers |
|---|---|---|---|---|
| **nitrylex** basic | nitrile, powder-free, for single use, dark blue | a'100 | XS - XL | RD30105001-05_3373 |
| | | a'200 | XS - XL | RD30084001-05_3373 |
| | nitrile, powder-free, for single use, violet | a'100 | XS - XL | RD30106001-05_3373 |
| | | a'200 | XS - XL | RD30098001-05_3373 |
| **Basic UDI-DI:** 5906615 RD NS N PF 9C | | | | |
| **Intended use:** gloves intended for use in the medical field to protect patient and user from cross-contamination, intended to be used on one individual during a single procedure | | | | |

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices. The products described above are classified as medical device class I, rule 5, according to Annex VIII of the Regulation (EU) 2017/745 and comply with European standards **(see Table 1).**

The products described above are 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 European standards **(see Table 1)**.

The products described above are subject to the EU type-examination (Module B) under EU type-examination certificate no. **(see Table 1)** issued by notified body **(see Table 1).**

Products are also subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) or conformity to type procedure based on quality assurance of the production process (Module D), under surveillance of the notified body **(see Table 1).**

MERCATOR

| Table 1 | | | | | |
|---|---|---|---|---|---|
| Reference numbers | Compliance with European standards [MD] | Compliance with European standards [PPE] | EU type-examination Certificate number – Module B | Notified Body – Module B | Notified Body – Module C2/D |
| RD30105001-05_3373<br>RD30084001-05_3373<br>RD30106001-05_3373<br>RD30098001-05_3373 | EN 455-1:2020+A1:2022<br>EN 455-2:2015<br>EN 455-3:2015<br>EN 455-4:2009<br>EN ISO 15223-1:2021<br>EN ISO 20417:2021 | EN ISO 21420:2020<br>EN ISO 374-1:2016+A1:2018<br>EN ISO 374-2:2019<br>EN 16523-1:2015+A1:2018<br>EN ISO 374-4:2019<br>EN ISO 374-5:2016 | 2777/14815-03/E70-01 | Module B:<br>Satra Technology Europe Limited (2777) | Module D:<br>Satra Technology Europe Limited (2777) |

Date and place of issue:
11.03.2023, Kraków

Signed on the behalf of the Manufacturer:

Leszek Garbacz
Regulatory and Documentation Manager

Issued to:

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

Notified Body: 2777

SATRA customer number: P21130

# EU Type-Examination Certificate

## Certificate number: 2777/14815-03/E70-01

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. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

**Product reference:**

Nitrylex ® classic
Nitrylex ® basic
Nitrylex ® white
Nitrylex ® black

**Description:**

Examination and protective gloves, nitrile, powder-free, disposable, non-sterile.

Colours: blue, violet, dark blue, white, black

**Sizes**:
(XS-XXL)

**Classification:**

| EN ISO 374-1:2016+A1:2018/Type B | Level | EN ISO 374-4:2019 Degradation % |
|---|---|---|
| 40% Sodium hydroxide (K) | 6 | -68.1 |
| 30% Hydrogen peroxide (P) | 2 | 30.5 |
| 37% Formaldehyde (T) | 5 | 9.5 |

| EN ISO 374-5:2016 | Level |
|---|---|
| Protection against Bacteria and Fungi | Pass |
| Protection against Viruses | Pass |

Standards/Technical specifications applied**:**
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0296241/2012, CHM0298100/2020/EN/A, CHM0298100/2020/EN/B
SGS: CH:TX:1142011147, CH:TX:1142011145-1, CH:TX:1142011148
TUV: 7191234075-CHM20-02-TSL, 7191235025-EEC20-WBH_CR1, 721652920

Signed on behalf of SATRA:

Geoff Graham

**Date of issue:** **11/03/2023**
**Expiry date:** **20/07/2025**

# 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. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (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 manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
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, or UK 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 the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.