



Issued to:

Mercator Medical (Thailand) Ltd
88/8 Moo.12
Tambon Kampaengphet
Amphur Rattaphum
Songkhla 90180
Thailand

Notified Body: 2777

SATRA customer number: P19011

EU Type-Examination Certificate

Certificate number: 2777/12470-05/E00-00

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 Classic +
Nitrylex Classic Long
Nitrylex Black
Nitrylex
Mcare

Description:

Powder Free Nitrile Examination Gloves in Black, Blue, Violet Blue, Cobalt Blue, Green, Magenta, Pink and White

Sizes:

XS – 4101
S – 4102
M – 4103
L – 4104
XL – 4105
XXL – 4106

Classification:

| EN ISO 374-1:2016 Type B | Level | EN 374-4:2013 |
|---------------------------|-------|---------------|
| 40% Sodium hydroxide (K) | 6 | 2.6% |
| 30% Hydrogen peroxide (P) | 2 | 52.8% |
| 37% Formaldehyde (T) | 5 | 20.0% |

EN ISO 374-5:2016

| | |
|---------------------------------------|------|
| Protection against bacteria and fungi | pass |
| Protection against viruses | pass |

EN 388: 2016

| | Level |
|----------------------|-------|
| Abrasion Resistance | 0 |
| Blade Cut Resistance | 0 |
| Tear Resistance | 0 |
| Puncture Resistance | 0 |
| TDM Cut Resistance | X |

Standards/Technical specifications applied:

EN ISO 374-1:2016+A1:2018; EN ISO 21420:2020; EN ISO 374-5:2016; EN 388:2016

Technical reports/Approval documents:

SATRA: CHM0276315/1840/3/SPT, CHM0278273/1847/LH, CHM0276315/1840/LH/O, CHM0276315/1840/LH/N, CHM0276315/1840/LH/P, CHM0276315/1840/LH/M, CHM0283479/1914/JG, SPC278179/1847, SPC0294086/2003, CHM0297987/2020/SPT
CHM0301781/2035/EN/Issue 2

Signed on behalf of SATRA:

Quincey Brown

Date first issued: 29/03/2019

Date of issue: 07/04/2021

Expiry date: 07/04/2026

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.