

[dokument sporządzono na oryginalnym papierze SATRA TECHNOLOGY]

[logotyp: SATRA]

Wydano dla: **Mercator Medical S.A.**
Ul. H. Modrzejewskiej 30
31-327 Kraków
Polska

Jednostka Notyfikowana: 2777

Klient SATRA nr: P19011

Certyfikat Badania Typu UE

Numer 2777/12470-07/E02-01

Niniejszy Certyfikat Badania Typu UE obejmujący następujące grupy produktów, został wydany w oparciu o badania przeprowadzone zgodnie z odpowiednimi normami / specyfikacjami technicznymi oraz ocenę dokumentacji technicznej. Został wydany zgodnie z Modułem B Rozporządzenia 2016/425 dotyczącego środków ochrony indywidualnej. Grupy produktów wykazały, że w sposób satysfakcjonujący spełniają obowiązujące zasadnicze wymagania dotyczące zdrowia i bezpieczeństwa, jako produkty Kategorii III.

Produkt referencyjny:

nitrylex classic
nitrylex classic+
nitrylex black
nitrylex basic
nitrylex one by one

Opis:

Diagnostyczne i ochronne rękawice nitrylowe, bezpudrowe do jednorazowego użytku, niesterylne.
Kolory: czarny, niebieski, fioletowy, ciemnoniebieski

Rozmiary:

XS
S
M
L
XL
XXL

Klasyfikacja:

EN ISO 374-1:2016+A1:2018 (Typ B)

40% Wodorotlenek sodu (K)
30% Nadtlenek wodoru (P)
37% Formaldehyd (T)

Poziom

6
2
5

EN ISO 374-4:2019
Degradacja %

2.6%
52.8%
20.0%

EN ISO 374-5:2016

Ochrona przeciwko bakteriom i grzybom
Ochrona przeciwko wirusom

Spełnia
Spełnia

Zastosowane normy / specyfikacje techniczne:

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

Raporty Techniczne / zatwierdzone dokumenty:

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

Podpisano w imieniu SATRA: [odręczny, nieczytelny podpis] (Geoff Graham)

Data wydania: 27.03.2024
Data wygaśnięcia: 13.12.2028

SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Irlandia



Issued to:

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

Notified Body: 2777

SATRA customer number: P19011

EU Type-Examination Certificate

Certificate number: 2777/12470-07/E02-01

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 Classic +
Nitrylex Black
Nitrylex Basic
Nitrylex one by one

Description:

Examination and protective gloves, nitrile, powder-free, disposable, non-sterile,
colours: black, blue, violet, dark blue

Classification:

Sizes:

XS
S
M
L
XL
XXL

EN ISO 374-1:2016+A1:2018 Type B

40% Sodium hydroxide (K)
30% Hydrogen peroxide (P)
37% Formaldehyde (T)

Level

6
2
5

EN ISO 374-4:2019 Degradation

2.6%
52.8%
20.0%

EN ISO 374-5:2016

Protection against bacteria and fungi
Protection against viruses

Pass
Pass

Standards/Technical specifications applied:

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

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:

Geoff Graham

Date of issue: 27/03/2024
Expiry date: 13/12/2028

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 or UKCA 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.