

EU Type-Examination Certificate

Certificate number: 2777/10580-02/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:

Nugard
 Non-Sterile:
 10-050-1 Ex Small
 10-050-2 Small
 10-050-3 Medium
 10-050-4 Large
 10-050-5 Ex Large

Description:

Nitrile Examination Gloves Powder Free
 Available in the following colours: Light blue, Black, Pink, Dark Blue, Blue, Pale Blue, Bright Pink, Green, Yellow, Turquoise, White, Blue (Violet)

Classification

EN ISO 374-1:2016 Type B

Sodium hydroxide 40% (K)
 Ammonium hydroxide 25% (O)
 Hydrogen peroxide 30% (P)
 37% Formaldehyde (T)

Level

6
 0
 3
 5

EN 374-4:2013 Degradation %

-4.2
 41.8
 32.9
 30.3

Sterile:

329-021-1 Ex Small
 329-021-2 Small
 329-021-3 Medium
 329-021-4 Large
 329-021-5 Ex Large

EN ISO 374-5:2016

Protection against bacteria and fungi
 Protection against viruses

Level

Pass
 Pass

Additional product codes:

GloveTEC Powder free:
 Nit-TE-GLO-(size-XS-XL)

Manufacturing sites:

Sentiex Sdn Bhd,
 No.1 Jalan Hi-Tech 12,
 Zon Industri Fasa 3,
 Kulim Hi-Tech Park, Kulim,
 09000 Kedah,
 Malaysia

Terang Nusa (M) Sdn Bhd,
 1, Jalan 8, Pengkalan,
 Chepa 2 Industrial Zone,
 Kota Bharu,
 Kelantan, 16100,
 Malaysia

Standards/Technical specifications applied:

EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016; EN 421: 2010 (excluding clause 4.3)

Technical reports/Approval documents:

SATRA: SPC0203338/1216, SPC0203338/1216/RS, CHM0261099/1733/EN/A, CHM0261099/1733/EN/B, CHM0263084/1741/EN/B/Issue 2, CHM0261099/1733/EN/C, SPC0269979/1816/2, CHM0270477/1818/EN/C

Signed on behalf of SATRA:



Geoff Graham



Pete Doughty

Date first issued: 13/06/2018

Date of issue: 05/12/2019

Expiry date: 13/06/2023

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.