Issued to:

Hartalega NGC Sdn Bhd
No 1, Persiaran Tanjung
Kawasan Perindustrian Tanjung
43900 Sepang
Selangor Darul Ehsan
Malaysia

Notified Body: 2777

SATRA customer number: P1144

EU Type-Examination Certificate

Certificate number: 2777/11578-04/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. 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:

Nitrile Powder Free Examination Gloves

Description:

≥ 2.2 mil Powder Free Nitrile disposable five fingered glove
Available in a standard minimum 240mm length or a longer cuff variant of 280mm, available as sterile (Gamma & X-ray) or non-sterile.

Sizes:

6 (XS)
7 (S)
8 (M)
9 (L)
10 (XL)
11 (XXL)

Classification:

EN ISO 374-1:2016+A1:2018 / Type B	Level	EN ISO 374-4:2019
40% Sodium Hydroxide (K)	6	-25.7%
30% Hydrogen Peroxide (P)	2	44.8%
37% Formaldehyde (T)	5	-17.1%

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; EN 421: 2010 (excluding clause 4.3)

Technical reports/Approval documents:
SATRA: CHM0264532/1746/EN/A; CHM0264532/1746/EN/B; CHM0272837/1827/LC/JH/A/Issue 2; SPC0232012/1505 Issue 2; CHM0268337/1810/EN; CHM0259706/1728/SPT; CHM0260437/1730/EN; CHM0264532/1746/EN/C; SPC0339493/2242/1; CHM0334576/2229/CC; CHM0334576/2229/SPT Issue 2; SPC0337444/2236/2; CHM0350835/2323/2; CHM0350835/2323/1, CHM4563B3J0 2342 1
SGS: CH:TX:1342045578; CH:TX:1342045581; CH:TX:1342045582; CH:TX:1342045583; CH:TX:1342045584; CH:TX:1342045585

Signed on behalf of SATRA:

Kayleigh Aylward

Date first issued: 22/11/2018
Date of issue: 09/12/2024
Expiry date: 09/12/2029

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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.

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