# MODULE D CERTIFICATE

## Issued To

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

Has been found to conform to the requirements of Annex VIII (Module D) of the PPE Regulation (EU) 2016/425 – Conformity to type based on quality assurance of the production process, for the manufacture and distribution of non-sterile powdered and powder-free natural latex and nitrile examination gloves, non-sterile powder-free polychloroprene examination gloves and sterile surgical gloves.

| Standards | Module B Certificates* |
|---|---|
| EN ISO 374-1:2016+A1:2018 | 2777/10475-XX/E00-00 |
| EN ISO 374-4:2019 | 2777/11080-04/E01-XX |
| EN ISO 374-5:2016 | 2777/11080-XX/E00-00 |
| EN ISO 21420:2020 | 2777/11513-XX/E00-00 |
| EN 421:2010 (Exc. Clause 4.3) | 2777/11578-XX/E00-00 |
| | 2777/11581-XX/E00-00 |
| | 2777/11723-XX/E00-00 |
| | 2777/11724-XX/E00-00 |
| | 2777/11755-XX/E00-00 |
| | 2777/11763-XX/E00-00 |
| | 2777/11900-XX/E00-00 |
| | 2777/12985-XX/E00-00 |
| | 2777/13883-XX/E00-00 |
| | 2777/14052-XX/E00-00 |
| | 2777/17920-XX/E00-00 |
| | 2777/22702-XX/E00-00 |
| | 2777/22900-XX/E00-00 |
| | 2777/24319-XX/E00-00 |
| | 2777/24550-XX/E00-00 |
| | 2777/25023-XX/E00-00 |
| | 2777/25664-XX/E00-00 |
| | 2777/25665-XX/E00-00 |
| | 2777/25678-XX/E00-00 |
| | 2777/25962-XX/E00-00 |
| | 2777/26318-XX/E00-00 |
| | 2777/26860-XX/E00-00 |
| | 2777/26929-XX/E00-00 |
| | 2777/27052-XX/E00-00 |
| | 2777/27176-XX/E00-00 |

* Where ‘XX’ denotes the Module B certificate issue number

**Date of first issue** 21st December 2023 **Expiry Date** 20th December 2028
**Latest Issue** 26th September 2025

Signed on behalf of SATRA Technology Europe Ltd – Notified Body Number: 2777

*The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard which will be monitored by: SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P Ireland - Tel: +353 (0) 1 437 2484 Web: www.satra.com*



Heruntergeladen von Gast (IP 216.73.217.10) am 25.11.2026 um 00:22 Uhr · sana.swiss

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

**Certificate Validity**

Subject to annual surveillance and ongoing conformity.
The certificate holder is responsible for ensuring that the notified body is advised of changes to any aspect of the overall process utilised in the manufacture of the product; failure to do so could invalidate the certificate in respect of product manufactured following the introduction of such changes.

| Date | Comments | Satra Reference No. |
|---|---|---|
| 21st December 2023 | Year 1 initial Module D audit from the 28th to 29th Nov 2023. | STE0351110 |
| 20th May 2024 | Module D certificate revision to include new certificates. | STE2005802 |
| 15th October 2024 | Year 2 surveillance audit from the 12th to 13th September 2024. | STE2009209 |
| 21st November 2024 | Module D certificate revision to include new certificates. | STE2016186 |
| 26th September 2025 | Year 3 surveillance audit from the 9th to 10th September 2025. | STE2028439 |

**Date of first issue** 21st December 2023 **Expiry Date** 20th December 2028
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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.

Please note:

1. Products covered by this certificate are classified by Regulation (EU) 2016/425 as category III Personal Protective Equipment and as such CE Marking is reliant on current compliance with Annex VIII Module D of this Regulation.
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 Module B certificates' technical file.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on the relevant module B certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained 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 the authorities.
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 (EU) 2016/425 on Personal Protective Equipment.

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