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 216.73.217.12) am 08.11.2026 um 23:28 Uhr · sana.swiss

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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

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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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