

## MODULE D CERTIFICATE

### Issued To

Anhui Intco Medical Products Co., Ltd

No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province, China

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 disposable nitrile, vinyl and synmax vinyl exam gloves in a range of colours and sizes.

### Standards

EN ISO 374-1:2016+A1:2018

EN ISO 374-4:2019

EN ISO 374-5:2016

EN ISO 21420:2020

EN 421:2010

(Radioactive contamination only)

### Module B Certificates\*

2777/14715-XX/E00-00

2777/14815-XX/E00-00

2777/15661-XX/E00-00

2777/22223-XX/E00-00

2777/25453-XX/E00-00

2777/26538-XX/E00-00

\* Where 'XX' denotes the Module B certificate issue number

This certificate is only valid if supported by a module D audit report issued by SATRA that is less than 12 months old.

**Date of first issue** 29<sup>th</sup> September 2025

**Date Issued** 29<sup>th</sup> September 2025

**Valid Until** 28<sup>th</sup> September 2026

**SATRA Reference** STE2025077



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](http://www.satra.com)



# 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 on page 1 of this certificate.
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.