



Notified Body 2777

# PPE REGULATION (EU) 2016/425 MODULE D CERTIFICATE

Certificate number: STE0326521

This is to certify that:

MacDonald & Taylor Healthcare  
Unit 6, Cranford Court,  
Hardwick Grange, Woolston, Warrington  
WA1 4RX

Production site:  
MacDonald & Taylor Healthcare  
Unit 6, Cranford Court,  
Hardwick Grange, Woolston, Warrington  
WA1 4RX

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 a range of disposable coveralls with welded seams manufactured from non-woven polypropylene with a valid type examination certificate issued under module B of Regulation (EU) 2016/425 on Personal Protective Equipment to one or more of the following standards.

EN 14126: 2003, Protective clothing. Performance requirements and tests methods for protective clothing against infective agents

EN 14605: 2005 +A1: 2009, Protective clothing against liquid chemicals. Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

EN ISO 13982-1: 2004+A1: 2010, Protective clothing for use against solid particulates. Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)

EN 13034: 2005+A1: 2009, Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)

EN 1149-5: 2018, Protective clothing. Electrostatic properties. Material performance and design requirements

EN 13688: 2013, Protective clothing. General requirements

Dated: 1<sup>st</sup> March 2023

This certificate is valid until: March 2024

For and on behalf of SATRA Technology Europe Limited

*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.satraeurope.com](http://www.satraeurope.com)



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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 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.