Issued to:

Finess Healthcare Group Co.,Ltd
No.1503 A1 Block,No.203 Lantian Road
315000 Ningbo
China

Notified Body: 2777

SATRA customer number: P20133

EU Type-Examination Certificate

Certificate number: 2777/18656-01/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:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

FN-IG0102060xxx

Suffixes:
201,202, 203, 204, 205, 206, 207, 208, 209, 101, 102, 103, 104, 105

Description:

Isolation gown in 45g.m^{-2} (± 5g.m^{-2}) Non-woven polypropylene + polyethylene laminate with either knitted or elastic cuffs, tie/tape fastenings at the rear of the neck and waist.

Available colours: Yellow, Light Green, Blue, Olive Green and White

Classification:

EN 14126:2003	**Class**
Resistance to penetration by contaminated liquids under hydrostatic pressure (ISO 16603:2004 & ISO 16604:2004)	6
Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids (ISO 22610:2018)	6
Resistance to penetration by contaminated liquid aerosols (ISO 22611:2003)	3
Resistance to penetration by contaminated solid particles (ISO 22612:2005)	3

EN 13034:2005 Type 6 [PB]	**Class**
Abrasion Resistance	1
Tear Resistance	2
Tensile Strength	1
Puncture Resistance	1
Seam Strength	2

	Liquid Repellency	**Liquid Penetration**
10% Sodium Hydroxide	3	3
30% Sulphuric Acid	3	3
O-Xylene	2	3
Butan-1-ol	3	3

Standards/Technical specifications applied:
EN 14126:2003; EN ISO 13688 :2013; EN 13034:2005+A1:2009; EN 14325:2004

Technical reports/Approval documents:
BTTG: E-017720/A1, E-017720/B1
HygCen: B 26616a

Signed on behalf of SATRA: Jacque Glasspool

Date first issued: 23/09/2021
Date of issue: 23/09/2021
Expiry date: 23/09/2026

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 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.