



Personal Protective Equipment Regulation (EU) 2016/425

Certificate

Module B EU Type-Examination

Manufacturer

Allied International Trading Limited (Trading As Supertouch)

Unit 3 Rabone Park Rabone Lane Smethwick West Midlands B66 2NN GB

Product Description:

SUPERTEX AS DISPOSABLE COVERALL

Product Code:

SDS-60101-7

Technical File Reference:

Huaxin-2021-001/V1/2021.Jun.04

Harmonised Standard(s):

EN ISO 13688:2013; EN ISO 13982-1:2004+A1:2010 (Type 5); EN 13034:2005+A1:2009 (Type 6);
EN 1073-2:2002 (TIL Class 1); EN 1149-5:2018

Technical Specification:

Not applicable

Certificate Number: SH01517

Issued by: Shirley® (Notified Body No. 2895 for Regulation (EU) 2016/425)

First issue: 05 January 2024 **Date of Issue:** 05 January 2024 **Expiry:** 14 August 2025

Authorised by

K Bolton

Senior Certification Officer

The attached schedule of approval forms part of this certificate.

Note: The validity of this certificate can be confirmed by contacting the Issuing Office:
Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13
Unit 21, Clonsaugh Business & Technology Park, Dublin 17, ROI

Tel: +353 (0) 01894 1448 email: info@shirley.ie website: www.shirley.ie



Shirley® is a trade name of Shirley Technologies (Europe) Limited. Registered Office: Sky Business Centre, Office 13, Unit 21, Clonsaugh Business Park, Dublin 17. A company registered in Ireland with company number 627888. VAT Number IE 3571932TH. The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.

Copyright © 2021 Shirley Technologies (Europe) Limited. All rights reserved.
OFC00907 STEL - v4 - 05.10.2021 - Approval Level 1



Schedule of Approval
Certificate Number: SH01517

First Issued:	05 January 2024	Page No:	2 of 5
Issue date:	05 January 2024	Issued by:	Shirley® (Notified Body No. 2895)
Expiry date:	14 August 2025	Shirley® ref:	SH-032873
Manufacturer:	Wuhan Huaxin Medical Products Co., Ltd.		
Technical file ref:	Huaxin-2021-001/V1/2021.Jun.04		

Shirley®, specified as a "notified body" under the terms of the Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment, did undertake the relevant type approval procedures for the equipment identified below which was found to be in compliance with the relevant provisions of Annex V (Module B) of the Regulation and with the applicable essential health and safety requirements, subject to any conditions in the schedule attached hereto.

The certificate relates specifically to the PPE items described and depicted in the manufacturer's Technical File, copies of which are held by the manufacturer and Shirley®, and not to any other items.

The certificate remains valid unless cancelled or revoked, provided the conditions in the attached schedule are complied with and the equipment remains satisfactory in service.

Description of product

SUPERTEX AS DISPOSABLE COVERALL consisting of:

SDS-60101-7

Available in the following materials:

Main Fabric: 100% polypropylene with anti-static finish (55 gsm) (White)

CONTINUED ON PAGE 3



Schedule of Approval
Certificate Number: SH01517

First Issued:	05 January 2024	Page No:	3 of 5
Issue date:	05 January 2024	Issued by:	Shirley® (Notified Body No. 2895)
Expiry date:	14 August 2025	Shirley® ref:	SH-032873

Manufacturer: Allied International Trading Limited (Trading As Supertouch)
Technical file ref: Huaxin-2021-001/V1/2021.Jun.04

Manufacturers Technical Specification

Not Applicable.

Limitations of Use

- Usage, maintenance and storage as per manufacturer's instructions.
- The above listed garment meets the requirements of EN 1149-1:2006 and EN 1149-5:2018 for electrostatic dissipative protective clothing, however it may not be suitable for use in explosive atmospheres, as indicated by the manufacturers user information

Observations

- Not Applicable.

CONTINUED ON PAGE 4



Schedule of Approval
Certificate Number: SH01517

First Issued:	05 January 2024	Page No:	4 of 5
Issue date:	05 January 2024	Issued by:	Shirley® (Notified Body No. 2895)
Expiry date:	14 August 2025	Shirley® ref:	SH-032873

Manufacturer: Allied International Trading Limited (Trading As Supertouch)
Technical file ref: Huaxin-2021-001/V1/2021.Jun.04

Approval Documents

- Design test report No. E-031506/A
- Fabric test report Nos. PPE 114278(2)/AW/07; 50/00165/A1/PJH; 50/00165/A2/PJH; PPE 114278(1)/AW/07; SL52205254615601TX; SL52315318631301TX
- Garment test report Nos. 602-01306(d); 602-01306(b); 17RA00987
- Innocuousness test report Nos. 29521; SHAT02039153

CONTINUED ON PAGE 5



Schedule of Approval
Certificate Number: SH01517

First Issued:	05 January 2024	Page No:	5 of 5
Issue date:	05 January 2024	Issued by:	Shirley® (Notified Body No. 2895)
Expiry date:	14 August 2025	Shirley® ref:	SH-032873

Manufacturer: Allied International Trading Limited (Trading As Supertouch)

Technical file ref: Huaxin-2021-001/V1/2021.Jun.04

Terms and Conditions associated with the issue of this EU Type-Examination Certificate

1. This certificate is issued subject to Shirley®'s standard terms of business, available from our website.
2. Production is limited to the site(s) listed in the manufacturer's Technical File, copies of which are held by the manufacturer and Shirley®, and not to any other production site(s).
3. The client must implement appropriate changes as notified by Shirley®.
4. The client must ensure the certified product is representative of the ongoing manufactured product.
5. The client must make provision for access to relevant documents and records.
6. The client must investigate complaints associated with the certified products. Records of such complaints, and actions taken, must be kept by the client and made available to Shirley® when requested.
7. The client must only make claims consistent with the scope of certification,
8. The client must not make any misleading or unauthorised comments regarding the certified product or the certification body.
9. The client must upon suspension, withdrawal, or termination of certification discontinue the use of all advertising matter that contains any reference thereto and take action to return this certificate to Shirley®.
10. The client must comply with the requirements for the use of the notified body number as detailed below.
11. Any change to the product or quality manual / quality plan shall be immediately notified to Shirley®.
12. This certificate is issued in the English language only. It is the responsibility of the Manufacturer / Authorised Representative to obtain and supply language versions acceptable to the country where the product is to be sold. This certificate remains the property of Shirley® and will be withdrawn if any of the conditions attached to its issue are not complied with.
13. The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No 765/2008 and for category III PPE, followed by the number of the notified body involved in production control monitoring (Module C2 or D).
14. This certificate does not authorise the use of the Mark of Conformity (the 'CE mark'), which may only be affixed to the above type approved equipment and a Manufacturer's Declaration of Conformity issued when Module C2 or D of the Regulation is fully complied with and controlled by a written agreement with a notified body.

Use of Notified Body Number

1. The Notified Body Number must only be used
 - a. In direct association with products or systems covered by this Type-Examination Certificate.
 - b. by holder(s) of the Certificate.
2. Use of Shirley® Notified Body Number does not extend to other companies which are:
 - a. part of the same corporate group as the Certificate holding company: or
 - b. named in a Certificate, for example as a supplier.
3. Particular care must always be taken to avoid the association of the Shirley® Notified Body Number with other products or systems or schemes and with claims or information not contained in the Shirley® document.

If any of the above requirements are not met Shirley® will seek to suspend, withdraw or terminate this certificate.

END OF SCHEDULE