



Compliance Report

Applicant: [REDACTED]
Address: [REDACTED] Xiantao City, Hubei
Province, China.

Product: Coverall, Surgical Gown, Lab Coat, Cover Gown, Face Mask,
Cap, Shoe Cover, Sleeve Cover, Apron, Cover Chair, Lady
Gown, Howie Coat, Pyjama or Scrubs

Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

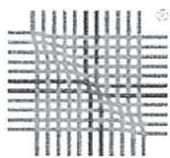
Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02288
Initial Issue Date: 21 Jan 2018

Tony Chen

General Manager (Signature)



Test Report 16RA08838

of **05/09/2016**

Messrs

XIANTAO - HUBEI - CN

Samples and identifications

Sample 16LA13707

Receipt date: **02/08/2016**

Sample receiving date: **02/08/2016**

Description: **Nonwoven fabric SF strong resistance air permeable film**

Composition: **100% polypropylene + film 100% polyethylene**

Mass per unit area: **63 g/m²**

Sampling carried out by: **customer**

This Test Report consists of the following results

90134 Protective clothing. Penetration by biologically contaminated aerosols

Protective clothing. Penetration by biologically contaminated aerosols

Product standard	UNI EN 14126:2004
Test method	ISO/DIS 22611:2003 + UNI EN 14126:2004 Par. 4.1.4.3
Name of test microorganism	Staphylococcus aureus (ATCC 6538 LOT: Mecconti/Kariosafe 3331303)
Test equipment	Perspex box with Collison atomizer
Specimens dimensions	Diameter 25 mm
Number of specimens	4
Pretreatment	No
Test began on:	29/08/2016
Test ended on:	31/08/2016

Results for sample 16LA13707

	UM	result
Micro-organisms extract to membrane REFERENCE (Value A)		
1st specimen	CFU	2560
2nd specimen	CFU	2280
3rd specimen	CFU	2130
4th specimen	CFU	2420
Average (A)	CFU	2347.5
Micro-organisms extract to membrane specimen (Value B)		
1st specimen	CFU	0
2nd specimen	CFU	0
3rd specimen	CFU	0
4th specimen	CFU	0
Average (B)	CFU	0.0
Penetration ratio (A/B)	Log10 CFU	> 5

Issue date
05/09/2016

Microbiological Laboratory Manager
dott. Giovanni Tanchis



PPE Testing and Certification Manager
arch. Marco Colli



End of Test Report 16RA08838