

## **Compliance Report**

Applicant:

Hubei Safe Way Protective Products Co., Ltd.

Address:

NO.118 Pengchang Avenue, Xiantao City, Hubei Province,

China.

Product:

Coverall, Lab Coat, Isolation Gown, Surgical Gown, Cap,

Face Mask, Shoe Cover, Oversleeves

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. 02278

Initial Issue Date: 06 Jan 2015

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General Manager

(Signature)



## Annex to Report (No. 02278)

## Hubei Safe Way Protective Products Co., Ltd.

Product Name	Туре
Coverall	18g-60g, S, M, L, XL, XXL, XXXL, XXXXL
Lab Coat	20g-50g, S, M, L, XL, XXL, XXXL, XXXXL
Isolation Gown	15g-40g, S, M, L, XL, XXL, XXXL, XXXXL
Surgical Gown	15g-40g, S, M, L, XL, XXL, XXXL, XXXXL
Сар	10-25g, 18", 19", 21", 24", 26", 28"
Face Mask	17.5*9cm, 12.5*9cm
Shoe Cover	25g-40g, 16, 18"
Oversleeves	25g-40g, 16, 18", 21"

This annex is only valid if attached to the report mentioned above.