



Compliance Report

Applicant: Xianning Yuanxiang Protection Products Co., Ltd.
Address: No.567 Yinquan Avenue, Wenquan Economic Development Zone, Xianning City, Hubei Province, China.

Product: Face Mask, Mob Cap, Isolation Gown, Surgical Gown, Lab Coat, Coverall, Patient Gown, Scrubs Suits, Bed Sheet, Bed Cover, Pillow Cover, Shoes Cover, Boot Cover, Apron, Sleeve Cover, Beard Cover, Underwear, Gloves, Surgical Packs, Drapes

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. 02516
Initial Issue Date: 16 May 2016

Tony Chen

General Manager (Signature)



Annex to Report (No. 02516)

Xianning Yuanxiang Protection Products Co., Ltd.

Product Name	Type
Face Mask	Child, Adult (or size custom-made)
Mob Cap	18", 21", 24", 26", 28"
Isolation Gown	M, L, XL, XXL, XXXL
Surgical Gown	M, L, XL, XXL, XXXL (or size custom-made)
Lab Coat	M, L, XL, XXL, XXXL (or size custom-made)
Coverall	M, L, XL, XXL, XXXL (or size custom-made)
Patient Gown	M, L, XL, XXL, XXXL
Scrubs Suits	M, L, XL, XXL, XXXL
Bed sheet	80cm*200cm, 80cm*210cm, 120cm*220cm, 150cm*220cm.
Bed Cover	80cm*200cm, 80cm*210cm. 120cm*220cm, 150cm*220cm.
Pillow Cover	50cm*60cm
Shoes Cover	15*36cm/ 15*39cm/ 15*41cm/ 15*40cm/ 14*38cm
Boot Cover	38*22cm/ 40*40cm
Apron	70*110cm/ 70*117cm/ 70*120cm/ 69*132cm/ 70*110cm/ 69*107cm/ 90*130cm/ 70*120cm/ 71*117cm/ 90*150cm/ 100*150cm/ 80*125cm
Sleeves	20*38cm/ 20*40cm/ 22*42cm/ 22*46cm/ 20*46cm
Beard Cover	18"
Underwear	S, M, L
Gloves	S, M, L
Surgical Packs	Custom-made
Drapes	Custom-made

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