



Compliance Report

Applicant: Xiantao Xinhengrun Plastic Products Co., Ltd.
Address: Gongtong Development Area, Xianhan Road, Pengchang Town, Xiantao, Hubei, China (Mainland). Zip code: 433000

Product: Caps, Face Mask, Sleeve Cover, Shoe Cover, Ear Cover, Gloves, Apron, Isolation Gown, Surgical Gown, Bed Sheet, Coverall, Food Cover, Lab Coat, Kimono, Underwear, Pedicure Liner, Sterilization Pouch, Pedicure Kit, Bags

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. 02919
Initial Issue Date: 3 Jul 2018



General Manager (Signature)



Annex to Report (No. 02919)

Xiantao Xinhengrun Plastic Products Co., Ltd.

Product Name	Type
Caps	(18"19"21"); (9g -- 30g); (15mic-50mic); (Single elastic, Double elastic), any size can be customized
Face Mask	17.5*9.5cm, (Ear loop or with Tie On); any size can be customized
Sleeve Cover	20*40cm, 20*42cm, 20*46cm, any size can be customized
Shoe Cover	15*36cm, 16*38cm, 15*41cm, any size can be customized
Ear Cover	6cm-20cm, any size can be customized
Gloves	S, M, L, XL
Apron	S, M, L, XL, XXL, XXXL, XXXXL; 24"x42", 28"x46", any size can be customized
Isolation Gown	S, M, L, XL, XXL, XXXL, XXXXL
Surgical Gown	S, M, L, XL, XXL, XXXL, XXXXL
Bed Sheet	80*180cm, 120cm*180cm, 120cm*220cm, 120cm*240cm, any size can be customized
Coverall	S, M, L, XL, XXL, XXXL, XXXXL
Food Cover	12-150cm
Lab Coat	S, M, L, XL, XXL, XXXL, XXXXL
Kimono	S, M, L, XL, XXL
Underwear	S, M, L, XL
Pedicure Liner	S, M, L, XL, XXL
Sterilization Pouch	90*190mm, 90*200mm, 90*210mm, 90*260mm (Any other size can be customized)
Pedicure Kit	Buffer: 55*25*12mm,60*30*12mm,70*30*10mm or customized Pumice: 8*3.5*1.2cm,9*4.5*1.2cm, 10*4.8*1cm or customized. Nail file: 127*15*2mm Pusher: 105mm any size can be customized
Bags	PE bags, PP hand bags, Paper bags

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

This report is the property of NQA and should be returned to NQA upon request.