

Compliance Report

Applicant: Xiantao Lingyang Plastic Co., Ltd.
 Address: No.8 Hewan Industrial Park, Yanhe Road, Xiantao City, Hubei Province, P.R.China.
 Product: Nonwoven products: bouffant cap, mob cap, doctor cap, space cap, nylon mesh cap, working cap, face mask, paper face mask, isolation gown, surgical gown, lab coat, coverall, kimono, apron, suit, sauna cloth, visitor gown, shoe cover, boot cover, oversleeve, beard cover, pants, shopping bag, underwear, full cape, bed sheet, bed cover, pillow cover, patient gown, snood cap, peaked cap, sock cover, disposable cape, Non-woven bra, disposable hair band, disposable slipper.
 PE/CPE products: shoe cover, boot cover oversleeves, shower cap, raincoat, lab coat, apron, surgical gown, bed cover, disposable poncho, disposable glove, CPE gown
 PVC products: apron, oversleeves, shoe cover, boot cover, bed cover
 Type: Nonwoven, PE/CPE, PVC
 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. 02503

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Tony Chen

General Manager (Signature)

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