



Compliance Report

Applicant: XIANTAO YUNJI PROTECTION PRODUCTS CO., LTD.
Address: INDUSTRIAL ZONE, GUOHE COUNTY, XIANTAO,
HUBEI, CHINA

Product: NON-WOVEN PRODUCT (PP OVERALL WHITE,
ISOLATION GOWNS, PP VISITORS GOWNS, ROUND
NURSE CAPS, FACE MASK, SHOE COVER, WASH
GLOVE, WIPE GLOVE)
PLASTIC PRODUCT (PE SLEEVE, CPE SHOE COVER, PE
GLOVE)

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. 03015
Initial Issue Date: 18 Feb 2019

General Manager (Signature)