

Verification of Conformity

Applicant: XIANTAO SANDA INDUSTRIAL CO.,LTD
Address: NO.46 GOLDEN AVENUE,XIANTAO,HUBEI,CHINA
Product(s): Coverall, Lab Coat, Shoe Cover, Pillow Case, Sleeve Cover, Apron,
Face Mask, Cap, Surgical Gown, Patient Gown, Isolation Gown, Bed
Sheet/Bed Cover
Type(s): See annex
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 Medical Device Directive (93/42/EEC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2016;
EN 1041:2013; EN ISO 10993-1:2009/AC:2010;
EN ISO 10993-5:2009; EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. 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.

SUNGO Cert GmbH



Executive Director
Issued: Dec. 10 2019
Cert. No.: EU158518
Expiration Date: Dec. 9 2024

Annex to Cert. No.: EU158518

Product Name	Type
Coverall	S,M,L,XL,XXL,XXXL,XXXXL or customized
Lab Coat	S,M,L,XL,XXL,XXXL,XXXXL or customized
Shoe Cover	17*42 cm,16*39 cm,16*40 cm or customized
Pillow Case	70*50 cm or customized
Sleeve Cover	20*40 cm, 22*46 cm or customized
Apron	72*118 cm or customized
Face Mask	17.5*9.5cm,16.5*9.5cm,14.5*9.5cm or customized
Cap	Clip cap,Strip cap, Bouffant cap, Nylon net cap, Doctor cap, Surgical cap,Snood cap,Space Cap
Surgical Gown	S,M,L,XL,XXL,XXXL,XXXXL or customized
Patient Gown	S,M,L,XL,XXL,XXXL,XXXXL or customized
Isolation Gown	S,M,L,XL,XXL,XXXL,XXXXL or customized
Bed Sheet/Bed Cover	80*200cm or customized

END OF THE ANNEX