



Verification of Conformity

Applicant: HuBei Maximum International Co.,Ltd.
Address: 152#, Pengchang Ave. Pengchang town, Xiantao city, Hubei province.433018. P. R. China
Product(s): Surgical Gown, Isolation Gown, Lab Coat, Coverall, Cap, Face Mask, Shoe Cover, Boot Cover, Bed Sheet, Pillow Case, Hairdressing Clothes, Beard Cover, Apron, Sleeve Cover, Spread Cover, Shopping Bag, Thermo Poncho, Gyn Skirt, Scrub Suits, Colonoscopy Shorts, Disposable Clothing
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 1041:2008+A1:2013; EN ISO 10993-12:2009/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



Annex to Cert. No.: EU190518

Product Name	Type
Surgical Gown	115*127, 115*137, 120*140, 130*150,
Isolation Gown	115*137, 120*140, 140*160, 158*160
Lab Coat	110*120,110*125,115*130,120*135,120*140, 125*140, 130*145
Coverall	158*116,160*120,168*128,173*134,181*142, 188*150,165*125,170*130,175*135,180*140, 185*145
Cap	18",21",24",62*13.5cm,62*9cm
Face Mask-	17.5*9cm
Shoe Cover	38*15cm,39*16cm,40*17cm
Boot Cover	40*40cm
Bed Sheet	240*140cm
Pillow Case	70*50cm
Hairdressing Clothes	100*140cm
Beard Cover	18",21"
Apron	110*70cm
Sleeve Cover	39*20cm
Spread Cover	210*180*20cm
Shopping Bag	According to the customer request

END OF THE ANNEX