



Verification of Conformity

Applicant: CARESTONE MEDICAL & PROTECTIVE PRODUCTS CO., LTD.
Address: 10F, Bldg13, Guangcaihuijie, Tianzhushan East Road, Anqing City, Anhui Province, China
Product(s): Shoe Cover, Boot Cover, Sleeve Cover, Coverall, Apron, PE Glove, Rain Coat, PE Hood, PE Pants, Shower Cap, Vinyl Glove, Latex Glove, Nitrile Glove, Endoscope Hood Set, Pouch, Cap, Face Mask, Beard Cover, Isolation Gown, Surgical Gown, Scrub Suit, Lab Coat, Mattress Cover, Bed Sheet, Pillow Case, Non woven Roll, Bandage, Hairband, Ear Cover, Dental Bibs, Kimono, Identification Bracelet, Bikini, Under Pad, Slipper, Kidney Tray, Urinal, Respirators, Goggles
Type(s): See Annex of 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 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 10993-12009/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

