



Verification of Conformity

Applicant: [REDACTED]
 Address: [REDACTED]
 Product(s): Short Pants, CPE Gown, Bed Sheet, Surgical Gown, Lab Coat,
 Coverall, Isolation Gown, Cap, Face Mask, Shoe/Boot Cover,
 Oversleeve, Apron, Beard Cover, Visitor Gown
 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 ISO 10993-1:2010; EN ISO 10993-5:2009;
 EN ISO 10993-10:2010

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.: EU169518

Product Name	Type
Face Mask	As requested
Coverall	S/M/L/XL/2XL/3XL/4XL/5XL
Surgical Gown	S/M/L/XL/2XL/3XL/4XL/5XL
Lab Coat	S/M/L/XL/2XL/3XL/4XL/5XL
Isolation Gown	S/M/L/XL/2XL/3XL/4XL/5XL
Cap	18",19",20",21", 24",64*12cm or as requested
Shoe/Boot Cover	As requested
Oversleeve	40*20cm,50*20cm,50*25cm, or as requested
Short Pants	As requested
Bed Sheet	As requested
CPE Gown	As requested
Apron	As requested
Beard Cover	16",18"
Visitor Gown	S/M/L/XL/2XL/3XL/4XL/5XL

END OF THE ANNEX