



Verification of Conformity

Applicant: Henan Yubei Sanitary Materials Co., Ltd
Address: Pudong Industrial Park, Changyuan County
Product(s): Masks, Protective Clothing, Isolation 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 1041:2008; EN ISO 10993-1:2010;
EN ISO 10993-5:2009; EN ISO 10993-10:2013;
EN 14683:2014; EN13795:2011+A1: 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: Mar. 22 2020
Cert. No.: EU211518
Expiration Date: Mar. 21 2025





Annex to Cert. No.: EU211518

Product Name	Type
Masks	Large Size、 Small Size
Protective Clothing	Type I、 Type II
Isolation gown	Type A、 Type B、 Type C

END OF THE ANNEX

DRAFT

Executive Director