



EC Declaration of Conformity



Regarding Medical Device Directive(93/42/EEC)

Manufacturer

Name: Shandong Shengquan New Material Co., Ltd

Address: Diaozhen Industrial Development Zone, Zhangqiu, Jinan, Shandong, China

Authorized representative in the European Community

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany

Product

Name: Disposable Medical Face Mask

Specification: 175mm × 95mm, 3-Layer

Classification: I

Rule: Annex IX rule 5 of the Directive 93/42/EEC

Conformity Assessment procedure: Annex VII of the Directive 93/42/EEC

We, the manufacturer declare on our solo responsibility that our product meets the requirements of Medical Device Directive and the following harmonized standards. EN ISO 14971:2012

EN ISO 15223-1:2016

ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2010

EN 1041:2008

EN 14683:2019

ISO 13485:2016

Place of issue: Jinan

Position: Management Representative

Signature :

Date:

Xiumei Zhang

2020.4.13