

File No: SQ-MDD-13



EC Declaration of Conformity Regarding Medical Device Directive(93/42/EEC)

Manufacturer

Name: Shandong Shengquan New Materials 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
Product Model: SMDP20605
Specification: 175mm × 95mm, 3-Layer
Classification: I
Rule: Annex IX rule 1 of the Directive 93/42/EEC
Conformity Assessment procedure: Annex VII of the Directive 93/42/EEC

We, the manufacturer declare on our sole responsibility that our product meets the requirements of Medical Device Directive and the following harmonized standards.

EN 14683:2019 Type IIR
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
ISO 13485:2016

Place of issue: Jinan

Position: Management Representative

Signature:

Date: Xiumei Zhang

Xiumei Zhang

2020.4.13