

Declaration of Conformity

according to Directive 93/42/EEC, on medical devices

Maker
(Name, Address) **Getein Biotech, Inc.**
No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

Authorized Representative
(Name, Address) **CMC Medical Devices & Drugs S.L.**
C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Medical device Single-Use Medical Face Mask (Non-Sterile)

Model /Type Type I

Classification Class I

Conformity assessment procedure 93/42/EEC Annex VII

Applicable standards EN ISO 14971:2019 EN ISO 13485:2016
EN ISO15223-1:2016 EN 1041:2008+A1:2013
EN ISO 10993-5:2009 EN ISO 10993-10:2013
ISO 22609:2004 EN ISO 11737-1:2018
EN 14683:2019

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's medical devices directive: 93/42/EEC Annex VII.

General Manager Enben Su

Nanjing, 16th Mar, 2020
(place and date of issue)


Enben Su
(name and signature or equivalent marking of authorized person)

CE