

EC DECLARATION OF CONFORMITY



Name and address of the manufacturer: Changzhou Shuangma Medical Devices Co., Ltd.
San He Kou Development Zone, Zhengjiang Training
Changzhou, Jiangsu, China.213115

EC Authorized Representative: CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18 CP 29006, Málaga-Spain

We declare under our sole responsibility that

the medical device: Medical face mask
Model: Planar ear loop
Type I

UMDNS code: 12447

Standard: EN 14683:2019

Product photograph



Basic UDI-DI: /

Trade name: /

of class: Class I

according to annex VIII of Regulation EU 2017/745(MDR) and Directive 93/42/EEC(MDD)

Meets the provisions of the Regulation EU 2017/745(MDR) and Directive 93/42/EEC(MDD). The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: Annex II, Annex III of EU 2017/745

Declaration of Conformity is valid until: / 2021-03-10

Changzhou, 2020-03-10

Changzhou 2020-3-10
Place, date/

Xu Aiping, General Manager

Xu aiping
Name and function