



EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gentier Medical (Shanghai) Inc.**
No. 18, Jianding Road, Fengjing Town, Jinshan District
201502 Shanghai, China

Name and address of the European 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 Masks**

Product code NS2R-01, MS2R-02

Intended purpose This product meets European Standard EN 14683, Type IIR. As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. It is designed to be fluid resistant to splash and spatter of blood and other infectious materials. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

of class: I

according to Annex VIII of Regulation (EU) 2017/745

meets the provisions of the Regulation (EU) 2017/745 which apply to it. The declaration of conformity is valid in connection with the batch-related "final inspection report" of the device.

Conformity assessment procedure: **EU Declaration of Conformity referred to in MDR Article 19**

Certificate: **NA**

Notified Body: **NA**

Shanghai, 2020-03-16

Place, date

曹李伟, Sales Manager

Name and function