Medical Face Masks Declaration of Contomity MDR Medical Face Masks Date: 2020-03-16 Rev. A/0 EU DECLARATION OF CONFORMITY Name and address of the manufacturer: Gentier Medical (Shanghai) Inc. No. 18, Jianding Road, Fenging Town, Jinshan District 2015/02 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 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 minim the direct transmission of infective agents between staff and patien is designed to be fluid resistant to splash and spatier of blood and other infectious materials. Medical face mask, may also be intended to be worn by patients a other persons to reduce the risk of spread of infections, particularly epidemic or pandemic situations. of class: I according to Annex VIII of Regulation (EU) 2017/745 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			Documentation no.	Gemtier/CE-34 - 11	
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	Certificate:	NA			
Notified Body: NA	Notified Body:	NA			

Shanghai, 2020-03-16

Place, date



Name and function