

GEMTIER MEDICAL (SHANGHAI) INC.	Documentation no.	CE-34NS-11DOC Rev-1
	EC Declaration of conformity	English
Medical face mask	Date: 2020-04-07	Rev. A/1

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Gemtier 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
info@cmcmedicaldevices.com

We declare under our sole responsibility that

the medical device: Medical Face Mask
Product code: NS2R-01, NS2R-02 (PH-REF: 600 0000 15)

of class: **I, Non-Sterile**

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration of conformity is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

Notified Body: No involvement of a Notified Body is required for this device.

Shanghai, China 2020-04-07

Place, date



Name and function

Cao Jinhua, Sales Manager