EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:

Gemtier Medical (Shanghai) Inc.
No. 18, Jianding Road, Fengjing Town, Jinshan District
201502 Shanghai, China
sales@gemtier.com
SRN: /

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
SRN: ES-AR-000000293

the medical device: **Medical Face Mask (EN 14683, Type IIR, Non-Sterile)**

Product code: NS2R-02 (PH-REF: 60000015, 60000021)
Basic UDI-DI: 4052199545561

GMDN code

4 052199 545561

GMDN code: 35177

Classification (MDR, Annex VIII): **Class I, Rule 1**.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare under our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable regulations, directives:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008 +A1:2013, EN ISO 14971:2019, EN 62366-1:2015 +AC:2015, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, ASTM D4169-16, MDCG 2019-15 rev.1

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

Signature:

CAO LAIHUA, Sales Manager — Shanghai China, 2021-04-23

Name and function — Place, date

GEMTIER MEDICAL (SHANGHAI) INC. 上海金塔医用器材有限公司 中国 上海 CHINA SHANGHAI