EC Declaration of Conformity

CERTIFICATE OF EC

According to

EU Directive 93/42/EEC

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provision of Council directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer Registered Name **: RENOSEM Co., Ltd**

Product Name **: Low Temperature Plasma Gas Sterilizer**

GMDN Code No **: 36305 Sterilizer, gas, plasma, low temperature**

Model Name **: RENO-S130 or FINO-1300**

Address **: 2nd~5th Floor.,54,Samjak-ro 133beon-gil,Bucjeon-si, Gyeonggi-do, Republic of Korea**

Classification **: Class IIb (MDD 93/42/EEC, Annex IX Rule 15)**

Conformity Assessment Route **: Annex II, Excluding Section 4, MDD 93/42/EEC As amended by Directive 2007/47/EC**

Notified Body **: SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium**

Standards applied **: ISO13485:2016, EN ISO14971:2012, EN 1041:2008, EN ISO 15223-1:2016, ISO 14937:2009, EN 62304 :2006/ AC:2008, EN 61010-1:2010, EN 61010-2-040:2015, EN 61326-1:2013**

EC Representative **: CMC Medical Devices & Drugs S.L. C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain**

Certification No. : **KR19/ 81826213**

Date of issue **: 2021. 12. 24.**

CE 1639

Signature :

Digitally signed by Latîşev Anastasia
Date: 2025.08.13 18:51:41 EEST
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Kwang-Sik Lee / CEO