EC Declaration of Conformity

RENOSEM

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 **: Sterilization Agent**

① GMDN Code No : **44835, Hydrogen peroxide device sterilant**

Model Name **: RENO-SA,RENO-SA10,RENO-SA20,RENO-SA90, FINO-SA30, FINO-SA130, FINO-SA20**

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, EN1041:2008, EN ISO 15223-1:2016, ISO14937:2009**

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

Certification No. : **KR19/ 81826213**

Date of issue **: 2022. 2. 22.**

Digitally signed by Latîşev Anastasia
Date: 2024.03.26 14:53:51 EET
Reason: MoldSign Signature
Location: Moldova

CE 1639

Signature : Kwang-Sik Lee

Kwang-Sik Lee / CEO