



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 N° 18, CP 29006, Málaga, Spain**

Certification No. : **KR19/ 81826213**

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



Signature : 
Kwang-Sik Lee / CEO