

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.

CE₁₆₃₉

Signature: Kungfank Lee

Kwang-Sik Lee / CEO