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 **: Low Temperature Plasma Gas Sterilizer**

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

Model Name **: RENO-S90**

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, EN 61010-1:2001, EN 61010-2-040:2005, EN 61326-1:2006, CISPR11:2009/ A1: 2010**

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 : Kwang-Sik Lee

Kwang-Sik Lee / CEO

Certificate KR09/01233

The management system of

RENOSEM Co., Ltd.

2nd~5th Floor, 54, Samjak-ro 133beon-gil, Bucheon-si,
Gyeonggi-do, Republic of Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and Manufacture of Low Temperature Hydrogen Peroxide Sterilizer, Hydrogen Peroxide Sterilizing Agent and Washer Disinfector.

This certificate is valid from 20 February 2021 until 20 February 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 February 2024
Issue 11. Certified since 20 February 2009

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 **f** +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Expert in Infection Control
Renosem

March 21, 2023

Official Letter of Notification

Subject: Notification of CE MDD extension

To whom it may concerns,

We Renosem Co., Ltd. who are proven and reputed manufacturers of RENO Low Temperature Hydrogen Peroxide Gas Sterilizers, do hereby announces the official information in regard to the extension of CE Medical Device Directive.

Recently, concerning our former CE MDD certificate dated to be expired in Feb 2023 and the previous notification regarding the suspension of CE MDD registration, we were officially informed by SGS Korea, our notified body that extension of CE certificate has been implemented. The expiry of existing CE certificate of Renosem for all RENO models shall be extended to **December 31st** 2028 without issuance of new certificate.

In reference with the documentation of the following:

- CE Certificate of Renosem Co., Ltd. dated 25 March 2020
- Amendment of regulation published in Official Journal of the European Union
- Letter of notification from SGS Belgium
- MDR Contract of Renosem and SGS or derogation document

Until issuance of derogation document, the document shall be substituted with MDR Contract.
Until issuance of derogation document, the documentation shall be **provided upon request** due to its sensitivity.

In case of any further inquiry, please reach out to your point of contact for Renosem Co., Ltd.
We highly appreciate your cooperation and support.

For and behalf of
Renosem Co., Ltd.

Kang Ki Hun.

Kenny Kang,
Director, Renosem Co., Ltd.

T +82 32 222 0100 F +82 32 222 0110
2nd~5th, 54, Samjak-ro 133beon-gil, Bucheon-si, Gyeonggi-do, Rep. of KOREA, 14452
www.renosem.com

Dear Manufacturers,

As you may already know, the EU parliament voted last week in favour of extending the deadlines of the MDR (EU) 2017/745 transition. This decision was mainly taken to avoid any medical device shortage on the European Market.

The approved text is granting an automatic extension of the MDD certificate validity till 31st December 2027 for Class III & Class IIb implantable devices and 31st December 2028 for other devices.
However, the following conditions are to be met:

1. Devices continue to comply with MDD
2. There are no significant changes in design and intended purpose
3. The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, nor to other aspects of the protection of public health
4. Manufacturers must have a quality management system compliant with MDR (EU) 2017/745 article 10(9) before 26 May 2024
5. Manufacturers or their authorized representatives has lodged a formal application with a notified body before 26 May 2024 and signed a contract covering devices for transition before 26 September 2024 for the devices covered within the MDD certificate.

For MDD certificates that have already expired, the aforementioned condition 5 is replaced by either having a contract signed for MDR with a Notified body or having a derogation issued by a European competent authority before certificate has expired.

The voted text is emphasizing that appropriate surveillance activity for the maintenance of the MDD certificate shall be conducted by the Notified Body having issued the MDD certificate except if an agreement is put in place with the Notified body in charge of MDR conformity assessment. In SGS, we will conduct at least systematic regular on-site surveillance to maintain issued MDD certificate. We will continue conducting technical file reviews on a sampling basis for Class IIa and IIb products over the transition period. In addition, based on future guidance received from the commission or our risk assessment we may include partial assessment of Class III devices as well within this period. To allow the above, we need to establish a new contract and associated proposal with you if you wish to extend the validity of your MDD certificate within the transition period. Please note that the validity of the current certificate is extended and that NO new certificate will be issued as it is against the law.

As the conditions are determined based on lodging an MDR application and signing an MDR contract with a Notified Body, we are strongly encouraging you to contact your local medical device office to initiate the process of MDR conformity assessment as soon as possible to avoid last minute rush. We shall manage start of transition to MDR of all our MDD certified manufacturers in the next 18 months, and while the time is limited, we will do our best to support you transition within your defined timelines.

However, since signing contract can take up in between 2 to 6 months, we would require those who wish to go through this process to submit application to us as soon as possible.

For any further question, please contact your local medical device office.

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

EC Certificate Full Quality Assurance System: Certificate KR19/81826213

The management system of

RENOSEM Co., Ltd.

2nd~5th Floor, 54, Samjak-ro 133beon-gil, Bucheon-si,
Gyeonggi-do, Republic of Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Low Temperature Hydrogen Peroxide Sterilizer for Invasive and Non-invasive Medical Devices (Model:RENO-D50, RENO-S30, FINO-300, RENO-S30A, RENO-S130, FINO-1300, RENO-S20, FINO-200, RENO-S130D, RENO-S90);
Hydrogen Peroxide Sterilizing Agent for Use in RENO Series and FINO Series Hydrogen Peroxide Sterilizer (Model: RENO-SA, FINO-SA30, RENO-SA10, FINO-SA130, RENO-SA20, FINO-SA20, RENO-SA90)
Washer Disinfector(Model: BLUNIX60)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 25 March 2020 until 20 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 20 February 2009
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered KR/SEL Y-PC/08201

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com