

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

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