

EC Certificate Full Quality Assurance System: Certificate KR09/01232

The management system of

## RENOSEM Co., Ltd.

Unit 103-806, 397, Seokcheon-ro, Bucheon-si,  
Gyeonggi-do, 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 Disinfectant (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 20 February 2018 until 20 February 2023 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 17 February 2021  
Issue 13. Certified since 20 February 2009

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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Unit 103-806, 397, Seokcheon-ro, Bucheon-si,  
Gyeonggi-do, 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  
Disinfectors.**

This certificate is valid from 20 February 2018 until 20 February 2021  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 17 February 2021

Issue 9. 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](http://www.sgs.com)



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