

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 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 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

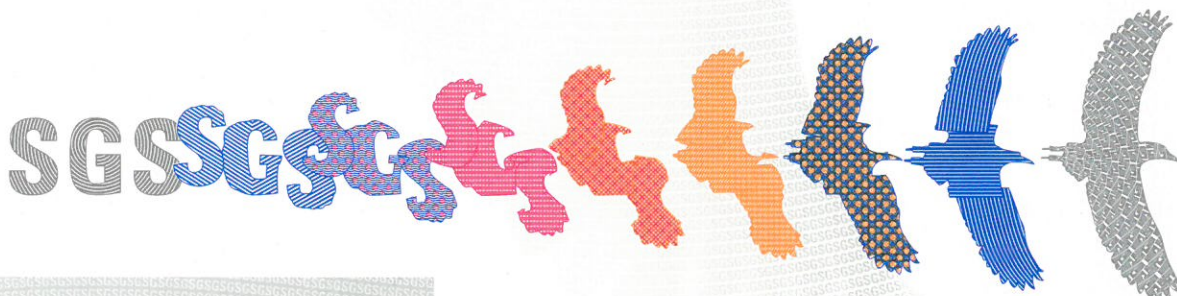


SGS United Kingdom Ltd, Notified Body 0120

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

SGS CE 02 0215

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



Certificate KR09/01233

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

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
Disinfectant.**

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

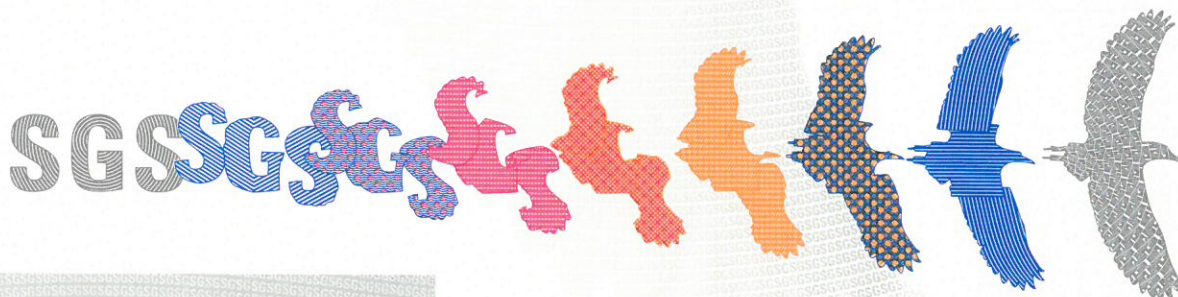
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



0005

SGS 13485 2016 0417

Page 1 of 1



This document is issued by the Company subject to its General Conditions of
Certification Services accessible at www.sgs.com/terms_and_conditions.htm.
Attention is drawn to the limitations of liability, indemnification and jurisdictional
issues established therein. The authenticity of this document may be verified at
<http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>.
Any unauthorized alteration, forgery or falsification of the content or appearance
of this document is unlawful and offenders may be prosecuted to the fullest
extent of the law.