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

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