EU Quality Management System Certificate KR25/00000036

The management system of

RENOSEM CO., LTD.

Room #822, #823, #824, #608, #212, 301 Bupyeong-daero, Bupyeong-gu, Incheon-si, 21315,
Republic of Korea
SRN Number: KR-MF-000023080

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 07 March 2025 until 07 March 2030 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 07 September 2029

Issue 1. Certified since 07 March 2025

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

Digitally signed by Latîşev Anastasia
Date: 2026.05.25 16:08:01 EEST
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Location: Moldova
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EU Quality Management System Certificate KR25/00000036, continued

RENOSEM CO., LTD.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa devices:

MDA0317, MDS1009

Low Temperature Hydrogen Peroxide Sterilizer for Invasive and Non-invasive Medical Devices, Model;

RENO-S20 [BUDI-DI: 880929378887PL]
RENO-S30 [BUDI-DI: 880929378001M8]
RENO-D50 [BUDI-DI: 880929378002MA]
RENO-S90 [BUDI-DI: 880929378893PF]
RENO-S130 [BUDI-DI: 880929378017MP]
RENO-S130D [BUDI-DI: 880929378888PN]
RENO-S Plus [BUDI-DI: 880929378942P3]
FINO-1300 [BUDI-DI: 880929378017MP]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - KR/SEL/Y-PC/08201 - S2A 1.6 + TFR 7.7
Authorized representative name and address (if relevant): CMC Medical Devices & Drugs SL. ; C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Previous certificate number: N/A
Change in between this certificate and previous one: N/A