EU Quality Management System Certificate KR23/00000154

The management system of

RF Medical Co., Ltd.

#502 ~ 507, 511, 601 World Meridian 254 Beot kkot-ro, Geumcheon-gu, Seoul, Republic of Korea

SRN Number: KR-MF-000012647

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 21 September 2023 until 21 September 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 March 2028

Issue 1. Certified since 21 September 2023

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
SGS Belgium NV NB 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

RF Medical Co., Ltd.

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIb

MDA0312, MDS1009, EMDN: Z120109

Medical Electrosurgical Generators;
M-3004 – BUDI-DI: 880014291601B7
V-1000 – BUDI-DI: 880014291602B9

Medical Electrosurgical Generators for the Treatment of Varicose Veins;
V-700 – BUDI-DI: 880014291603BB

MDA0312, MDS1005, EMDN: K020101

Sterile Single-use Mono-polar Electrodes for Electrosurgical Units;
Big-Tip (including bendable type) - BUDI-DI: 014291604JS
JET-TIP (including bendable type) - BUDI-DI: 014291607JY
RFT - BUDI-DI: 014291606JW
EMT - BUDI-DI: 014291605JU
VCT (including BMDT, and CST) - BUDI-DI: 014291608K2
HEMOTIP - BUDI-DI: 014291609K4

Sterile Single-use Bi-polar Electrodes for Electrosurgical Units;
VVT - BUDI-DI: 014291611JP
DBT - BUDI-DI: 014291610JM

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/211956 - S2A 9.6
Authorized representative name and address (if relevant): OBELIS S.A. Bd Général Wahis, 53, B-1030, Brussels, Belgium
Previous certificate number: N/A
Change in between this certificate and previous one: N/A