EC Certificate Full Quality Assurance System: Certificate KR19/81826202

The management system of

SHENB Co., Ltd.

SHENB bldg. 148 Seongsuiro, Seongdong-gu, Seoul, 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

The scope of registration appears on page 2 of this certificate

This certificate is valid from 06 April 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 22 February 2011

Certification is based on reports numbered KR/SEL Y-PC/10250

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

SHENB Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

High Frequency stimulator (Model : SH-312B, VIVALINE) for the treatment of muscle pain relief;

High Frequency Electrosurgical unit (Model : VIVACE, VIVACE II) for treatment of acne scars including associated hand piece, foot switch and sterile micro needle cartridge (Model: SH-TIP, SH-TIIPII);

High Frequency Electrosurgical unit (Model : VIRTUE RF) for treatment of acne scars including associated hand piece, foot switch and sterile micro needle cartridge (Model: SmartRF 36PIN TIP, SmartRF 36PIN TIP II)

High Frequency Electrosurgical unit (Model : ONIX) for treatment of acne scars and Osmidrosis and Primary Axillary Hyperhidrosis Including associated hand piece, foot switch and Sterile micro Needle Cartridge (Model: ONIX-TIP, ONIXTIP2);

Sterile needle-Free Injection System (Model: SHEMAX) for administration of medicines into the dermis Including associated Sterile Needle-Free Cartridge (Model:SHEMAX-NZ);

Plasma Surgical Unit (Model:PLADUO, PLASMADUO) for the treatment of acute and chronic sounds of skin tissues;

High Frequency Electrosurgical and Acupuncture Electrical Stimulator System (Model:SILSHAPE) for scar treatment with pain relief.

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.