EC Certificate Full Quality Assurance System: Certificate KR19/81826209

The management system of

DAESUNG MAREF CO., LTD.

(HQ & 1st Factory) 298-24, Gongdan-ro, Gunpo-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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 05 November 2020 until 10 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 10 July 2015
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered KR/SEL Y-PC/14403

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

DAESUNG MAREF CO., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

Intermittent Pneumatic Compression System for the treatment and prevention of lymphedema (Model: LF900, MK400L);

Digital Pneumatic Tourniquet System for the hemostasis during surgery (Model: DTS-3000);

Intermittent Pneumatic Compression System for the prevention of deep vein thrombosis and pulmonary embolism after surgery (Model: DVT-2600, DVT-4000S, DVT-PRO)

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.

Additional facilities

(Warehouse) 25-22, Hyundaikia-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, Korea

(2nd Factory) 1F, 298-21, Gongdan-ro, Gunpo-si, Gyeonggi-do, Korea