EC Certificate Full Quality Assurance System: KR15/02499

The management system of

DAESUNG MAREF Co., Ltd.

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 10 July 2015 until 10 July 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 January 2018
Issue 1. Certified since 10 July 2015

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

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 02 0315 M2

DAESUNG MAREF Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

Intermittent Pneumatic Compression System for the treatment and prevention of lymphedema (Model: DL1200H, LX7, LX9, MK300L, MK400L) ;

Digital Pneumatic Tourniquet System for the hemostasis after surgery (Model: DTS-2000S, DTS-2000W, DTS-3000) ;

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

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

(1st Factory) B1, 296, Gongdan-ro, Gunpo-si, Gyeonggi-do, Korea

(2nd Factory) 2F, 99, Sanbon-ro, Gunpo-si, Gyeonggi-do, Korea