DAESUNG MAREF CO.,LTD.
298-24, Gongdan-ro, Gunpo-Si, Gyeonggi-do, Korea

Web Site : www.dsmaref.com

EC Declaration of Conformity

Manufacture is exclusively responsible for the declaration of conformity.
Manufacturer :

DAESUNG MAREF CO.,LTD.
298-24, Gongdan-ro, Gunpo-Si, Gyeonggi-do, Korea
SRN No. : KR-MF-000008616

EC Representative :

KTR Europe GmbH
Mergenthalerallee 77, Eschborn, Hessen, 65760, Germany
Tel: +49(0) 6196 887170 Fax: +49(0) 6196 887 1728
SRN No. : DE-AR-000005685

*Device Name: Intermittent Pneumatic Compression system(GMDN Code: 10969 / EMDN Code : Z120607)
*Model Name: MK400L
*Classification: Class Ⅱa

Basic UDI-DI - MK400L : 880931567IPCRJ

Category	Ref No.	Part Name	Remark
Device	MK400L	Intermittent Pneumatic Compression system	

Classification : Class Ⅱa Rule 9 of Classification Criteria, Annex IX,
MDD 93/42/EEC as amended by Directive 2007/47/EC

Conformity Assessment Route :

MDD 93/42/EEC as amended by Directive 2007/47/EC (Annex Ⅱ Excluding Section 4)

We hereby declare that the complies with the Medical Devices Directive 93/42/EEC
as amended by Directive 2007/47/EC (and its relevant transposition into the national laws
of the Member States in which the device is intended to be placed on the market) using
Annex Ⅱ(Excluding Section 4) as the conformity assessment procedure via SGS (NB 1639) as the Notified Body.

The MK400L is not device incorporates, as an integral part, a substance or human blood derivative referred to Section 7.4 of Annex I.
The MK400L has not been used in the production tissues of animal origin covered by 2003/32/EC Directive.
The MK400L is not device incorporates, as an integral part, a substance which, if used separately may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC.

Applied Standard

MK400L is conformity with essential requirement and provision of Council Directive
2007/47/EC and are in conformity with the national standards transposing harmonized standards

EN 60601-1, EN 60601-1-2, EN 60601-1-6, EN 62304, EN/ISO 14971, EN 62366-1, EN 62366-2, EN/ISO 13485, EN 1041, ISO 7010, IEC 60417-1, EN/ISO 15223-1, EN 10993-1, EN 10993-5, EN 10993-10

Notified Body: Number 1639, SGS Belgium NV,
SGS House Noorderlaan 87 2030 Antwerp Belgium
Tel : +32(0)3 545-48-48 Fax : +32(0)3 545-48-49

EC certificate :	KR19/81826209
Expiration Date of EC certificate:	10. July. 2023
Start of CE-marking :	10. July. 2015
Place of issue :	Korea
Issue Date of DoC:	09. June. 2023
Expiration Date of DoC:	31. December. 2028

Statement
According to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 and Official Journal of the European Union of 20 March 2023, if the conditions in the paragraph 3c Article 120 are met, class IIa devices device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of Article 120 may be placed on the market or put into service until 31 December 2028.

Signature : 

Jae Hwa Lee, CEO
On DAESUNG MAREF CO.,LTD.

Attachments 1. S/N Information

Total Q'ty : 0

Model name	Serial No.	Remark