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.
(Head Office Laboratory, Service Center & 2nd Factory)
298-24, Gongdan-ro, Gunpo-si, Gyeonggi-do, Republic of Korea
(1st Factory)
32-33, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
(Warehouse)
3F, 50 LS-ro 115beon-gil, Gunpo-si, Gyeonggi-do, 15809, Republic of Korea

Manufacturer SRN. : KR-MF-000008616

EC Representative :

KTR Europe GmbH
Mergenthalerallee 77, 65760, Eschborn, Germany
Tel: +49(0) 6196 887170 Fax: +49(0) 6196 887 1728

Authorised representative SRN No. : DE-AR-000005685

Device Type	Category	Device Name (Model Name)	Classification	Remark
Intermittent Pneumatic Compression System for the treatment and prevention of lymphedema	Device Main body	MK400L	Class Ⅱa	GMDN Code: 44785
	Accessory	Compression Sleeve (IPC Sleeve)	Class Ⅰ	*Ref to the DoC (RND-R-DOC-110-01)*
		Tubing	Class Ⅰ	

Intended purpose :
The purpose of this system is to treatment and prevent of lymphedema by improving the blood circulation of patients.

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

No.	Name and version	Description
1	ISO 13485:2016 EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
2	IEC 60601-1:2005+A1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
3	IEC 60601-1-2:2014 EN 60601-1-2:2015	Medical electrical equipment Part 1: General requirements Section1.2 Collateral standard: Electromagnetic Compatibility
4	IEC 60601-1-6:2010+A1:2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance- Collateral standard : Usability
5	ISO 14971:2019 EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
6	IEC 62366-1:2015+A1:2020 EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
7	IEC 62304:2006+A1:2015 EN 62304:2006+A1:2015	Medical device software - Software life cycle process
8	ASTM D4169-23e1	Standard practice for performance testing of shippingcontainers and systems
9	ISO 7000:2019	Graphical symbols for use on equipment - Registered symbols
10	ISO 7010:2019	Graphical symbols - Safety colors and safety signs - Registered safety signs
11	ISO 20417:2026 EN ISO 20417:2026	Medical devices - Information to be supplied by the manufacturer

12	ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
13	EN 50419:2022	Marking of electrical and electronic equipment (EEE) in respect to separate collection of waste EEE (WEEE)

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:	20. April. 2026
NB Confirmation Letter Reference:	CLNB1639 - KR/SEL/Y-PC/14403

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 : 

Jai Wha Lee, CEO
On DAESUNG MAREF CO.,LTD.