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

Web Site : www.dsmaref.com

EU 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 No. : KR-MF-000008616

Authorised representative :

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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	LF900	Class Ⅱa	*Ref to the DoC (RND-R-DOC-103-01-02-06 or RND-R-DOC-103-01-02-06-50)*
		MK400L	Class Ⅱa	*Ref to the DoC (RND-R-DOC-104-01-02 or RND-R-DOC-104-01-02-50)*
	Accessory	Compression Sleeve (IPC Sleeve)	Class Ⅰ	Basic UDI-DI : 880931567IPCSLEEVEZH EMDN Code : Z12069080
		Tubing	Class Ⅰ	

4-chamber accessories (Use in conjunction with LF900)

Category	Ref No.	Part Name	Remark
Sleeve	4LAGL5A	LEG SLEEVE (L)	
	4LAGX40	LEG SLEEVE (XL)	
	4LAGY00	LEG SLEEVE (XXL)	
	4AAGF3A	ARM SLEEVE (F)	
	4WAGF1A	WAIST SLEEVE (F)	
	4SAGF5A	CENTER BODY SLEEVE (F)	
	4MDRF00	STRETCHING MAT 4 (F)	
	S401	OVER LAPPING LEG SLEEVE (S)	
	SW401	OVER LAPPING LEG SLEEVE (SW)	
	SXW401	OVER LAPPING LEG SLEEVE (SXW)	
	M401	OVER LAPPING LEG SLEEVE (M)	
	MW401	OVER LAPPING LEG SLEEVE (MW)	
	MXW401	OVER LAPPING LEG SLEEVE (MXW)	
	L401	OVER LAPPING LEG SLEEVE (L)	
	LW401	OVER LAPPING LEG SLEEVE (LW)	
	M403	OVER LAPPING HALF-LEG SLEEVE (M)	
	MW403	OVER LAPPING HALF-LEG SLEEVE (MW)	
	M402	OVER LAPPING ARM SLEEVE (M)	
	L402	OVER LAPPING ARM SLEEVE (L)	
	4VDRL00	OVER LAPPING ARM-CHEST SLEEVE (L)	
Tubing	1000370	SINGLE TUBING 2m	
	1000380	DOUBLE TUBING 2m	
	100050A	DISTRIBUTION TUBING 0.5m	
Other accessory	4ELGL02	LEG EXTENSION ZIPPER (L)	
	4ELGX01	LEG EXTENSION ZIPPER (XL)	
	4ELGY00	LEG EXTENSION ZIPPER (XXL)	
	4EAGF02	ARM EXTENSION ZIPPER (F)	
	4ECGF01	CENTER BODY EXTENSION ZIPPER (F)	

6-chamber accessories (Use in conjunction with MK400L)

Category	Ref No.	Part Name	Remark
Sleeve (6CH)	6LAGLA0	LEG SLEEVE (L)	
	6LAGXA0	LEG SLEEVE (XL)	
	6LAGYA0	LEG SLEEVE (XXL)	
	6AAGFA0	ARM SLEEVE (F)	
	6WAGFA0	WAIST SLEEVE (F)	
	6PRGF01	FULL BODY SLEEVE (F)	
Tubing	1000480	SINGLE TUBING 2m	
Other accessory	6ELGL30	LEG EXTENSION ZIPPER (L)	
	6ELGX30	LEG EXTENSION ZIPPER (XL)	
	6ELGY30	LEG EXTENSION ZIPPER (XXL)	
	6EAGF30	ARM EXTENSION ZIPPER (F)	

Intended purpose :

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

Classification :

The IPC Sleeve, Tubing are Class I device by Medical Devices Regulation 2017-745 of European Parliament and of the council of 5 April 2017 ANNEX VIII Rule 1.

Applied Regulation and Standards

We herewith declare that the above mentioned products are in conformity with Medical device Regulation(EU) 2017/745 and with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

Also, these are conformity with Genral Safety and Performance Requirements and in conformity with the below international standard, national standards, or(and) harmonized standards.

No.	Name & Version	Description
1	ISO 13485:2016 EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
3	ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
4	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
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	ASTM D4169-23e1	Standard practice for performance testing of shipping containers and systems
8	ISO 20417:2026 EN ISO 20417:2026	Information to be supplied by the manufacturer
9	ISO 15223-1:2021+A1:2025 EN ISO 15223-1:2021+A1:2025	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
10	ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols
11	ISO 7010:2019	Graphical symbols - Safety colours and safety signs - Registered safety signs

Statement

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Place of issue : KOREA

Date of issue : 29. April. 2026

Signature :

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