




CE/MDD DOC

Model Name MK400L
Doc. No. RND-R-DOC-104-01-02
Rev. No. 4
Rev. Date 2022.04.21



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0.1 Revision History

Rev. No.	일자 (Date)	내용 (Contents)	Prepared	Reviewed	Approved
0	2020.09.22	Fully revised due to product number change and add sleeve			
			2020.09.22	2020.09.22	2020.09.22
1	2020.12.01	Revised due to CE MDD certificate reissued			
			2020.12.01	2020.12.01	2020.12.01
2	2021.07.29	Revised due to SRN Number& Basic UDI-DI application			
			2021.07.29	2021.07.29	2021.07.29
3	2021.12.23	Revised due to correction of Basic UDI-DI			
			2021.12.23	2021.12.23	2021.12.23
4	2022.04.21	Revised due to addition of set list			
			2022.04.21	2022.04.21	2022.04.21



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)

*Model Name: MK400L

*Classification: Class IIa

Basic UDI-DI - MK400L : 880931567IPCSLEEVEZH

*For information on accessories and Sets, see Attachments

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, EN/ISO 13485, EN 1041, EN/ISO 15223-1

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
Start of CE-marking : 10. July. 2015
Place of issue : Korea
Date of issue : 21. April. 2022
Date of Expiration : 10. July. 2023



Signature :

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

Attachments 1. List of possible accessories included in the device

Category	Ref No.	Part Name	Remark
Sleeve	6LAGLA0	LEG SLEEVE(L)	
	6LAGLA1	LEG SLEEVE(L)	
	6LAGXA0	LEG SLEEVE(XL)	
	6LAGXA1	LEG SLEEVE(XL)	
	6LAGYA0	LEG SLEEVE(XXL)	
	6LAGYA1	LEG SLEEVE(XXL)	
	6AAGFA0	ARM SLEEVE(F)	
	6AAGFA1	ARM SLEEVE(F)	
	6WAGFA0	WAIST SLEEVE(F)	
	6WAGFA1	WAIST SLEEVE(F)	
	6PRGF01	FULL BODY SLEEVE(F)	
	6EAGF30	ARM EXTENSION ZIPPER(F)	
	6ELGL30	LEG EXTENSION ZIPPER(L)	
	6ELGX30	LEG EXTENSION ZIPPER(XL)	
	6ELGY30	LEG EXTENSION ZIPPER(XXL)	
Tubing	1000480	SINGLE TUBING(2m)	

Attachments 2. Set List

Set name	Ref No.	Set composition
MK400L BASIC SET	MK4L250-BL	1 DEVICE, 2 LEG SLEEVES, 2 SINGLE TUBINGS
MK400L BASIC SET	MK4L250-BX	1 DEVICE, 2 LEG SLEEVES, 2 SINGLE TUBINGS
MK400L FULL BODY SET	MK4L250-FB	1 DEVICE, 1 FULL BODY SLEEVES & EXTENSION ZIPPERS & 2 SINGLE TUBINGS
MK400L ARM SET	MK4L250-AL	1 DEVICE, 2 LEG SLEEVES, 1 ARM SLEEVE, 2 SINGLE TUBINGS
MK400L ARM SET	MK4L250-AX	1 DEVICE, 2 LEG SLEEVES, 1 ARM SLEEVE, 2 SINGLE TUBINGS