

EC Declaration of Conformity

Manufacture is exclusively responsible for the declaration of conformity.

Manufacturer: DAESUNG MAREF CO., LTD.

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EC Representative; DONGBANG AcuPrime Ltd

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Classification: Class IIa

according to the Rule 1(Compression Sleeve), Rule 9(Intermittent Pneumatic Compression system) of Classification Criteria, Annex IX , MDD 93/42/EEC as amended by Directive 2007/47/EC

*Device Name: Intermittent Pneumatic Compression system (GMDN Code: 16836)

Model Name: MK400L

Class IIa

*Device Name: Compression sleeve (GMDN Code: 33320)

Model Name: Sleeve (IPC)

Class I

Part no.	Part name	Part no.	Part name	Part no.	Part name
ACg0610	LEG SLEEVE (L)	ACg0612	WAIST SLEEVE	ACg0630	Leg (L size) Extension Zipper
ACg0610-1	LEG SLEEVE (XL)	ACg0615	FULL BODY SLEEVE	ACg0630-1	Leg (XL size) Extension Zipper
ACg0610-2	LEG SLEEVE (XXL)	ACg0615-1	FULL BODY SLEEVE (OL)	ACg0634	Full body Extension Zipper
ACg0611	ARM SLEEVE	ACg0631	Arm Extension Zipper		

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 Section4) as the conformity assessment procedure via SGS(NB 0120) as the Notified Body.

Applied Standard

MK400L & Sleeve (IPC) 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 62366, EN 62304, EN 14971, EN 13485, EN ISO 15223-1, EN 1041, EN 10993-1, EN 10993-5, EN 10993-10

Notified Body: Number 0120, SGS United Kingdom Limited,

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-EC certificate: KR15/02499

-Start of CE-marking: 10 July 2015

-Place of issue: Seoul, Korea

-Date of issue: 10 July 2018

-Date of Expiration: 10 July 2023



Signature :

President

On DAESUNG MAREF CO., LTD.