CE/MDD DOC

Digitally signed by Antonova Anna
Date: 2023.08.31 22:10:02 EEST
Reason: MoldSign Signature
Location: Moldova

Model Name	DTS-3000
Doc. No.	RND-R-DOC-201-01
Rev. No.	4
Rev. Date	2022.04.21

DS MAREF

DS MAREF	CE/MDD DOC	Model Name	DTS-3000
		Doc. No.	RND-R-DOC-201-01
		Rev. No.	4
		Rev. Date	2022.04.21

0.1 Revision History

Rev. No.	일자 (Date)	내용 (Contents)	Prepared	Reviewed	Approved
0	2019.12.23	First issued by changed the form, NB No. and Europe representative			
			2019.12.23	2019.12.23	2019.12.23
1	2020.12.03	Revised due to CE MDD certificate reissued			
			2020.12.03	2020.12.03	2020.12.03
2	2021.06.30	Revised due to HOSE length change and SRN Number& Basic UDI-DI application			
			2021.06.30	2021.06.30	2021.06.30
3	2021.12.22	Revised due to correction of Basic UDI-DI and added standard			
			2021.12.22	2021.12.22	2021.12.22
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: Digital Pneumatic Tourniquet system (GMDN Code: 14074)
*Model Name: DTS-3000
*Classification: Class Ⅱa

Basic UDI-DI - DTS-3000 : 880931567DTSS5

*For information on accessories and Sets, see Attachments

Category	Ref No.	Part Name	Remark
Device	DTS-3000	Digital Pneumatic Tourniquet 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 DTS-3000 is not device incorporates, as an integral part, a substance or human blood derivative referred to Section 7.4 of Annex I.
The DTS-3000 has not been used in the production tissues of animal origin covered by 2003/32/EC Directive.
The DTS-3000 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

DTS-3000 & Cuff(DTS) 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 60601-1-8, EN 62304, EN/ISO 14971, EN 62366, EN/ISO 13485:2016, EN 1041:2008, EN/ISO 15223-1, EN/ISO 17664, ISO 17665-1

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
Cuff	DTC-S02	SINGLE CUFF 40 X 7cm	
	DTC-S04	SINGLE CUFF 52 X 7.5cm	
	DTC-S05	SINGLE CUFF 61 X 9cm	
	DTC-S06	SINGLE CUFF 80 X 9cm	
	DTC-S07	SINGLE CUFF 86 X 10cm	
	DTC-S08	SINGLE CUFF 107 X 10cm	
	DTC-D04	DOUBLE CUFF 57 X 10cm	
	DTC-D05	DOUBLE CUFF 80 X 15cm	
	DTC-D06	DOUBLE CUFF 107 X 15cm	
	DTC-D07	DOUBLE CUFF 57 X 15cm	
	DTC-C25	CONE SINGLE CUFF 70 X 10cm	
	DTC-C26	CONE SINGLE CUFF 90 X 12cm	
	DTC-C27	CONE SINGLE CUFF 107 X 14cm	
	DTC-CD25	CONE DOUBLE CUFF 70 X 10cm	
	DTC-CD26	CONE DOUBLE CUFF 90 X 12cm	
	DTC-CD27	CONE DOUBLE CUFF 107 X 14cm	
	DTC-SA01	SILICONE BLADDER CUFF 30 X 11cm	
	DTC-SA02	SILICONE BLADDER CUFF 46 X 11cm	
	DTC-SA05	SILICONE BLADDER CUFF 61 X 11cm	
	DTC-SA06	SILICONE BLADDER CUFF 76 X 11cm	
	DTC-SA07	SILICONE BLADDER CUFF 86 X 11cm	
	DTS-SA15	SILICONE BLADDER CUFF 52 X 7cm	
Hose	1000180	RED MAIN HOSE (2m)	
	1000190	BLUE MAIN HOSE (2m)	
	1000200	GRAY MAIN HOSE (2m)	
IOP SENSOR	0100090	IOP SENSOR	

Attachments 2. S/N Information

Total Q'ty : 0

Model name	Serial No.	Remark

Attachments 2. Set List

Set name	Ref No.	Set composition
DTS-3000 (Double/2 channels) DEVICE SET	DTSW410-2	1 DEVICE, HOSE SET(1 RED, 1 BLUE, 2 GRAY), IOP SENSOR
DTS-3000 (Double/2 channels) BASIC SET	DS0204	1 DEVICE, 5 NO PINCH CUFFS (S05, S06, C26, D04, D05), HOSE SET, IOP SENSOR
DTS-3000 (Double/2 channels) SILICON BLADDER SET	DTSW410-SS	1 DEVICE, 5 SILICON BLADDER CUFFS CUFFS (SA02, SA05, SA06, SA07, SA15), HOSE SET, IOP SENSOR

EC Certificate Full Quality Assurance System: Certificate KR19/81826209

The management system of

DAESUNG MAREF CO., LTD.

(HQ & 1st Factory) 298-24, Gongdan-ro, Gunpo-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 05 November 2020 until 10 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 10 July 2015
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered KR/SEL Y-PC/14403

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

DAESUNG MAREF CO., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

Intermittent Pneumatic Compression System for the treatment and prevention of lymphedema (Model: LF900, MK400L);

Digital Pneumatic Tourniquet System for the hemostasis during surgery (Model: DTS-3000);

Intermittent Pneumatic Compression System for the prevention of deep vein thrombosis and pulmonary embolism after surgery (Model: DVT-2600, DVT-4000S, DVT-PRO)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

(Warehouse) 25-22, Hyundaikia-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, Korea

(2nd Factory) 1F, 298-21, Gongdan-ro, Gunpo-si, Gyeonggi-do, Korea

Certificate KR15/02498

The management system of

DAESUNG MAREF CO., LTD.

(HQ & 1st Factory) 298- 24, Gongdan-ro, Gunpo-si, Gyeonggi-do, 15809, Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities
Design, Development, and Manufacture of
Intermittent Pneumatic Compression System for the treatment and prevention of lymphedema;
Intermittent Pneumatic Compression System for the prevention of deep vein thrombosis and pulmonary embolism after surgery;
Digital Pneumatic Tourniquet System for the hemostasis during surgery;
Temperature therapy System for relief of pain, swelling, and edema;
Rehabilitation device for orthopedic improvement;

This certificate is valid from 03 April 2023 until 03 April 2026 and remains valid subject to satisfactory surveillance audits.

Issue 10. Certified since 10 July 2015
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

DAESUNG MAREF CO., LTD.

ISO 13485:2016
EN ISO 13485:2016

Issue 10
Sites
DAESUNG MAREF CO., LTD. (HQ & 1st Factory) 298- 24, Gongdan-ro, Gunpo-si, Gyeonggi-do, 15809, Korea
DAESUNG MAREF CO., LTD. (Warehouse) 25-22, Hyundaikia-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18576, Korea
DAESUNG MAREF CO., LTD. (Laboratory, Service Center & 2nd Factory) 1F, 2F, 4F, 298-21, Gongdan-ro, Gunpo-si, Gyeonggi-do, 15809, Korea