CE/MDD DOC

Model Name	DTS-3000
Doc. No.	RND-R-DOC-201-01
Rev. No.	1
Rev. Date	2019.12.24

DS MAREF	CE/MDD DOC	Model Name	DTS-3000
		Doc. No.	RND-R-DOC-201-01
		Rev. No.	1
		Rev. Date	2019.12.24

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	2019.12.24	Issued by the additional Tubing			
			2019.12.24	2019.12.24	2019.12.24

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

EC Representative :

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

Classification : Class Ⅱa Rule 9 of Classification Criteria, Annex IX,
MDD 93/42/EEC as amended by Directive 2007/47/EC

*Device Name: Digital Pneumatic Tourniquet system (GMDN Code: 14074)
*Model Name: DTS-3000
*Classification: Class Ⅱa

*Device Name: Tourniquet Cuff (GMDN Code: 17230)
*Model Name: Cuff (DTS)
*Classification: Class Ⅰ

Category	Ref No.	Part Name	Remark
Device	DTS-3000	Digital Pneumatic Tourniquet system	
Cuff	DTC-S02	SINGLE CUFF 40 X 7cm	
	DTC-S04	SINGLE CUFF 52 X 7cm	
	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	AC SINGLE CUFF 30 X 11cm	
	DTC-SA02	AC SINGLE CUFF 46 X 11cm	

	DTC-SA05	AC SINGLE CUFF 61 X 11cm	
	DTC-SA06	AC SINGLE CUFF 76 X 11cm	
	DTC-SA07	AC SINGLE CUFF 86 X 11cm	
	DTS-SA15	AC SINGLE CUFF 52 X 7cm	
Hose	1000180	RED MAIN HOSE (2m)	
	1000190	BLUE MAIN HOSE (2m)	
	1000200	GRAY MAIN HOSE (2m)	

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 62304, EN/ISO 14971, EN 62366-1, EN 62366-2, EN/ISO 13485, EN 1041, EN/ISO 15223-1, EN 10993-1, EN 10993-5, EN 10993-10

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 : Seoul, Korea
Date of issue : 16. Dec. 2019
Date of Expiration : 10. July. 2023

Signature :

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

Attachments 1. S/N Information

Total Q'ty : 0

Model name	Serial No.	Remark