



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

Web Site : www.dsmaref.com

EU Declaration of Conformity

Statement

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

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

Manufacturer SRN No. : KR-MF-000008616

Authorised representative :

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Authorised representative SRN No. : DE-AR-000005685

Category	Device Name (Model Name)	Classification	Remark
DTS Accessories	DTS-CUFF	Class I	Basic UDI-DI : 880931567CUFFMU EMDN Code : Z12139080
	HOSE	Class I	Basic UDI-DI : 880931567TUBINGVL EMDN Code : Z12139080
	IOP SENSOR	Class I	Basic UDI-DI : 880931567IOPS9 EMDN Code : Z12139080

Category	Ref No.	Part Name		Remark
		Type	Size (Dimensions)	
DTS-CUFF	DTC-S02	SINGLE CUFF	40 X 7cm	-
	DTC-S04		52 X 7.5cm	-
	DTC-S05		61 X 9cm	-
	DTC-S06		80 X 9cm	-
	DTC-S07		86 X 10cm	-
	DTC-S08		107 X 10cm	-
	DTC-D04	DOUBLE CUFF	57 X 10cm	-
	DTC-D05		80 X 15cm	-
	DTC-D06		107 X 15cm	-
	DTC-D07		57 X 15cm	-
	DTC-C25	CONE SINGLE CUFF	70 X 10cm	-
	DTC-C26		90 X 12cm	-
	DTC-C27		107 X 14cm	-
	DTC-CD25	CONE DOUBLE CUFF	70 X 10cm	-
	DTC-CD26		90 X 12cm	-
	DTC-CD27		107 X 14cm	-
	DTC-SA01	SILICONE BLADDER SINGLE CUFF	30 X 11cm	-
	DTC-SA02		46 X 11cm	-
	DTC-SA05		61 X 11cm	-
	DTC-SA06		76 X 11cm	-
	DTC-SA07		86 X 11cm	-
	DTC-SA15		52 X 7cm	-
	DTC-SA1243	SILICONE BLADDER SINGLE CUFF	30 X 11 cm (12 X 4.3 inch)	-
	DTC-SA1843		46 X 11 cm (18 X 4.3 inch)	-
	DTC-SA2443		61 X 11 cm (24 X 4.3 inch)	-
	DTC-SA3043		76 X 11 cm (30 X 4.3 inch)	-
	DTC-SA3443		86 X 11 cm (34 X 4.3 inch)	-
	DTC-SA2128		52 X 7 cm (21 X 2.8 inch)	-
	DTC-SA1228		30 X 7 cm (12 X 2.8 inch)	-
	DTC-SA4563	SILICONE BLADDER CONE SINGLE CUFF	110 X 16 cm (45 X 6.3 inch)	-
	DTC-CS1843		46 X 11 cm (18 X 4.3 inch)	-
	DTC-CS2443		61 X 11 cm (24 X 4.3 inch)	-
	DTC-CS3043		76 X 11 cm (30 X 4.3 inch)	-
	DTC-CS3443		86 X 11 cm (34 X 4.3 inch)	-
	DTC-CS4443		112 X 11 cm (44 X 4.3 inch)	-
	DTC-CD1855	SILICONE BLADDER CONE DOUBLE CUFF	46 X 14 cm (18 X 5.5 inch)	-
	DTC-CD2455		61 X 14 cm (24 X 5.5 inch)	-
	DTC-CD3055		76 X 14 cm (30 X 5.5 inch)	-
	DTC-CD3455		86 X 14 cm (34 X 5.5 inch)	-
	DTC-CD4475		112 X 19 cm (44 X 7.5 inch)	-
HOSE	1000180	RED MAIN HOSE	3m	-
	1000190	BLUE MAIN HOSE	3m	-
	1000200	GRAY MAIN HOSE	3m	-
IOP SENSOR	0100090	-	1m	-

Intended purpose :

DTS Accessories are intended for use with tourniquet device to occlude the blood flow to obtain hemostasis field during limb(s) surgery.

The intended purposes of each are as follows:

1. DTS-CUFF : It is worn on the patient's hemostasis and receives air pressure from the Tourniquet device.
2. HOSE : Connects the Tourniquet device and the cuff.
Transmits air pressure from the Tourniquet device to the DTS-CUFF.
3. IOP Sensor : Worn on the patient's finger or toe.
It is connected to the main body and informs the recommended pressure value to user.

Classification :

The DTS-CUFF, HOSE, IOP SENSOR 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

No.	Name and version	Description
1	ISO 13485:2016 EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory
2	ISO 14971:2019 EN ISO 14971:2019	Medical devices - Application of Risk management to medical devices
3	IEC 62366-1:2015 EN 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices
4	ASTM D4169	Standard practice for performance testing of shipping containers and systems
5	ISO 20417:2021 EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
6	ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
7	ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols

Place of issue : KOREA

Date of issue : 11 September, 2023



Signature :

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