

CE/MDR DOC

Model Name DTS CUFF
Doc. No. RND-R-DOC-210-01
Rev. No. 1
Rev. Date 2021.12.23



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0.1 Revision History

Rev. No.	일자 (Date)	내용 (Contents)	Prepared	Reviewed	Approved
0	2021.07.15	First issued by application of MDR			
			2021.07.15	2021.07.15	2021.07.15
1	2021.12.23	Revision due to Basic UDI-DI correction			
			2021.12.23	2021.12.23	2021.12.23



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

Web Site : www.dsmaref.com

EU 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
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Authorised representative :

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SRN No. : DE-AR-000005685

*Device Name: DTS CUFF (EMDN Code : Z12139080)

*Model Name: DTS CUFF

*Classification: Class I

*Device Name: HOSE (EMDN Code : Z12069080)

*Model Name: HOSE

*Classification: Class I

*Device Name: IOP SENSOR (EMDN Code : Z12139080)

*Model Name: IOP SENSOR

*Classification: Class I

Basic UDI-DI - DTS CUFF : 880931567CUFFMU

Basic UDI-DI - HOSE : 880931567TUBINGVL

Basic UDI-DI - IOP SENSOR : 880931567IOPSS9

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	

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.

Conformity Assessment Route :

EU DECLARATION OF CONFORMITY following the ANNEX II + ANNEX III + Article 19 of Medical Devices Regulation 2017-745 of European Parliament and of the council of 5 April 2017.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards.

All supporting documentations are retained under the premises of the manufacture.

Applied Standard

DTS CUFF, HOSE, IOP SENSOR is conformity with essential requirement and Medical Devices Regulation 2017-745 of European Parliament and of the council of 5 April 2017

EN/ISO 14971, EN 62366-1, EN/ISO 13485, EN/ISO 20417, EN/ISO 15223-1, EN/ISO 10993-1, EN/ISO 10993-5, EN/ISO 10993-10, EN/ISO 17664, EN/ISO 17665-1, EN/ISO 11737-1, EN/ISO 11737-2

Place of issue : KOREA

Date of issue : 23. Dec. 2021

Signature :



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

Attachments 1. S/N Information

Total Q'ty : 0

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