

## *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, 15809, Korea

**EC Representative; DONGBANG AcuPrime Ltd**

1 The Forrest Units, Hennock Road East Exeter, EX2 8RU, UK

Tel: +44-1392-829500 Fax: +44-1392-823232

**Classification: Class IIa**

**according to the Rule 1(Tourniquet cuff), Rule 9(Pneumatic Tourniquet system) 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

Class IIa

\*Device Name: Tourniquet cuff (GMDN Code: 17230)

Model Name: Cuff (DTS)

Class I

Part no.	Part name	Part no.	Part name
DTC-S02	SINGLE 40 X 7cm cuff	DTC-CD26	CONE DOUBLE 90X 12cm CUFF
DTC-S04	SINGLE 52 X 7.5cm CUFF	DTC-CD27	CONE DOUBLE 107X 14cm CUFF
DTC-S05	SINGLE 61 X 9cm CUFF	DTC-SA01	AC SINGLE 30 X 11cm CUFF
DTC-S06	SINGLE 80 X 9cm CUFF	DTC-SA02	AC SINGLE 46 X 11cm CUFF
DTC-S07	SINGLE 86 X 10cm CUFF	DTC-SA05	AC SINGLE 61 X 11cm CUFF
DTC-S08	SINGLE 107 X 10cm CUFF	DTC-SA06	AC SINGLE 76 X 11cm CUFF
DTC-C25	CONE SINGLE 70 X 10cm CUFF	DTC-SA07	AC SINGLE 86 X 11cm CUFF
DTC-C26	CONE SINGLE 90X 12cm CUFF	DTC-SA11	AC SINGLE 20 X 8.2cm CUFF
DTC-C27	CONE SINGLE 107X 14cm CUFF	DTC-SA12	AC SINGLE 20 X 2.5cm CUFF
DTC-D03	DOUBLE 40 X 7cm CUFF	DTC-SA13	AC SINGLE 40 X 7cm CUFF
DTC-D04	DOUBLE 57 X 10cm CUFF	DTC-SA14	AC SINGLE 52 X 6cm CUFF
DTC-D07	DOUBLE 57 X 15cm CUFF	DTC-SA15	AC SINGLE 52 X 7.5cm CUFF
DTC-D05	DOUBLE 80 X 15cm CUFF	DTC-SA16	AC SINGLE 86 X 15cm CUFF

DTC-D06	DOUBLE 107 X 15cm CUFF	DTC-SA17	AC SINGLE 107 X 15cm CUFF
DTC-D05	DOUBLE 80 X 15cm CUFF	DTC-DA18	AC DOUBLE 57 X 15cm CUFF
DTC-D06	DOUBLE 107 X 15cm CUFF	DTC-DA19	AC DOUBLE 80 X 15cm CUFF
DTC-CD25	CONE DOUBLE 70 X 10cm CUFF	DTC-DA20	AC DOUBLE 107 X 15cm CUFF

**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**

DTS-3000 & Tourniquet Cuff 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, IEC 62366-1, IEC/TR 62366-2, EN 62304, EN 14971, EN 13485, EN 1041, EN 980, EN 10993-1, EN 10993-5, EN 10993-10

**Notified Body:** Number 0120, SGS United Kingdom Limited,  
202b, Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom  
Tel: +44(0)1934 522917 Fax: +44(0)1934 522137

- EC certificate: KR15/02499
- Start of CE-marking: 10 July 2015
- Place of issue: Seoul, Korea
- Date of issue: 10 July 2015
- Date of Expiration: 10 July 2020

**Signature :**



**President**

on DAESUNG MAREF CO., LTD.