

COTRONIC Technology Limited

Declaration of Conformity

For the following products: TM03, TM08

Hereinafter is confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC as amended 2007/47/EC) conformity Route: Annex II, exclusion Section 4.

EN12470-3:2000 + A1:2009 EN60601-1:2006

EN60601-1-2:2007 EN60601-1-6:2010

EN60601-1-11:2015 EN62366:2008

ENISO10993-1:2009 ISO10993-5:2009 EN ISO10993-10:2009

ENISO15223-1:2012 EN1041:2008 EN ISO14971:2012

Conformity assessment Route: **Annex II excluding Section 4**

The following manufacturer is responsible for making this declaration:

Company Name: **COTRONIC Technology Ltd**

Company Address: **Floor4~6, Block 7, West of ZhouShi Road, XiXiang Street, BaoAn Zone**

Shenzhen, Guangdong, China

European Union representative: **WellKang Limited**

Company Address: **Suite B, 29 Harley Street, LONDON W1G 9QR, England, United Kingdom**

Notified body name: **DNV GL Nemko Presafe AS (NB No. 2460)** *

Notified body address: **Veritasveien 3, N-1363 Hovik Postbox 116, N-1300 Sandvika**



General Manager

2018-12-07

(Legal Signature)

(Position/title)

(Date)