

Cotronic Technology Limited

Declaration of Conformity

For the following products: TM01

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

EN60601-1-11:2010      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, Block7, 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 Høvik Postbox 116, N-1300 Sandvika



General Manage

2017-11-28

(Legal Signature)

(Position/title)

(Date)