

Declaration of Conformity

For the following products:

TM01

(Product Name)

Electronic thermometer

(Model Designation)

is hereinafter 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 by 2007/47/EC)

Applicable harmonized standards are:

[ISO 80601-2-56:2017+A1:2018](#) [EN60601-1:2006+A1:2013](#)

[EN60601-1-2:2015](#) [EN60601-1-6:2010](#)

[EN60601-1-11:2015](#) [EN62366:2008](#)

[ENISO10993-1:2009](#) [ISO10993-5:2009](#)

[EN ISO10993-10:2009](#) [ENISO15223-1:2016](#)

[EN1041: 2008](#) [EN ISO14971:2012](#)

[Directive 2011/65/EU\(ROHS\)](#)

The certificate CE number (9962-2017-CE-RGC-NA-PS)

The certificate of ISO 13485 number:(244303-2017-RGC-NA-PS)

Conformity Assessment Route:

Annex II excluding section 4 of Medical Device Directive

Notified Body:

DNV GL Presafe AS (NB No. 2460)

Veritasveien 3, 1363 Høvik, Norway

The following European Authorized Representative is stated to the declaration:

Company Name: WellKang Limited

Company Address: The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

The following manufacturer is exclusively 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.**



(Legal Signature)

General manager

(Position/title)

2020-9-17

(Date)