Declaration of Conformity

Manufacture Kangfu Medical Equipment Factory
Address No.380 Ningkang East Road,Yueqing, Zhejiang 325600, China

European Representative Lin Sun
Luxus Lebenswelt GmbH
Product Name：Digital Thermometers
Models PFT-3.7
Product Category IIa
The UMDNS code 14-032
Conformity Assessment Route Directive 93/42/EEC
We declare the compliance of the above medical device with the applicable requirements **rules10** of Appendix IX of Directive 93/42/EEC ： All the supporting documents and files are retained under the premises of the manufactures.
Simultaneously meets the requirement of the following Recognized Consensus Standards.

- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC60601-1-11:2015 Medical electrical equipment. Part 1-11:General requirements for basic safety and essential performance. Collateral standard:Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 10993-1:2009 Ophthalmic instruments -- Slit-lamp microscopes
- ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for ir vitro cytotoxricity
- ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO14971:2016 Medical devices-Application of risk management to medical devices
- ISO15223-1:2016 Medical devices--symbols to be used with medical device labels,labelling and information to be suppliedlied--part1:general requirements
- ISO 80601-2-56:2009 medical electrical equipment part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- IEC 62366-2007+A1-2014 Medical devices-Application of usability engineering to medical devices
- MEDDEV2.71 rev4 Clinical evaluation: guidelines for manufacturers and notified institutions under Directive 93/42/EEC and 90/385/EEC

Announcement Organization：TÜV SÜD Product Service GmbH
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Position：Quality Manager
Place：YUEQING