TaiDoc
泰博科技股份有限公司
TaiDoc Technology Corp.
新北市24888五股區五工二路127號B1-7樓
B1-7F., No.127, Wugong 2nd Rd., Wugu Dist., New Taipei City 24888, Taiwan
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EC Declaration of Conformity

We, TaiDoc Technology Corporation

B1-7F, No.127, Wugong 2nd Road, Wugu Dist., 24888 New Taipei City, TAIWAN

declare under our sole responsibility that the product:

Product Name	: Non-Contact Forehead Thermometer
Product Model	: TD-1242
Classification	: 93/42/EEC (Directive including 2007/47/EC)(MDD),
	: Annex IX, Section 3, Rule 10, Class IIa
Conformity Assessment Route	93/42/EEC (Directive including 2007/47/EC)(MDD),
	: Annex II, excluding (4)
EC Certificate Number	G1 052126 0043 Rev.03
European Representative	: MedNet EC-REP GmbH
	: Borkstraße 10, 48163 Münster , Germany
Notified Body (CE0123)	TÜV SÜD Product Service GmbH Ridlerstraße 65,
	: 80339 München, Germany
GMDN code	: 14035

to which this declaration relates is in conformity with the following standard(s) or other normative document(s):

ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
EN ISO 80601-2-56:2012	Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN 1041:2008+A1:2013	Information supplied by the manufacture of medical devices
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 60601-1:2006 +A1:2013 +A12: 2014	Medical electrical equipment. General requirements for basic safety and essential performance
IEC/EN 60601-1-11:2015	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for

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	medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1-2:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes
EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices
2011/65/EU	The restriction of the use of certain hazardous substances in electrical and electronic equipment

The object of this declaration described above is in conformity with Council Directive 93/42/EEC and Directive 2011/65/EU of the European Parliament and of the Council.

2020. 3. 31

Date of Issue

Jim Jan

Jim Jan

Management Representative