TaiDoc
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EC Declaration of Conformity

We, TaiDoc Technology Corporation

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

declare under our sole responsibility that the product

Product Name	:	Finger type pulse oximeter
Product Model	:	TD-8255
Classification	:	93/42/EEC(Directive including 2007/47/EC)(MDD), Annex IX, Section 3, Rule 10, Class IIb
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 Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany
GMDN code	:	45607

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.
IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for safety.
EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
ISO 80601-2-61:2011	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

IEC 60601-1-11:2010	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 14155-1:2003	Clinical investigation of medical devices for human subjects - Part 1: General requirements
EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements
IEC 60601-1-6 :2010+A1:2015	Medical electrical equipment. Part 1-6: General requirements for safety - Collateral Standard: Usability.
IEC 62366-1:2015	Medical devices. Application of usability engineering to medical devices
IEC 62304:2006+AMD1:2015	Medical device software -- Software life cycle processes
ISO 10993-1: 2018	Biological evaluation of medical devices. Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices. Tests for irritation and skin sensitization
ISO 10993-12:2007	Biological evaluation of medical devices. Sample preparation and reference materials

IEC 60601-1-8:2006+A1:2012	Medical electrical equipment - Part 1-8: General requirements forbasic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems inmedical electrical equipment and medical electrical systems
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
2011/65/EU	The restriction of the use of certain hazardous substances in electrical and electronic equipment.

2020. 5 7.

Date of Issue

Jim Jan

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Management Representative