TaiDoc
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TaiDoc Technology Corp.
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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	:	Multi-Functional Monitoring System
Product Model	:	TD-4216
Classification	:	98/79/EC (IVDD), Annex II, List B
Conformity Assessment Route	:	98/79/EC (IVD), Annex IV excluding section 4 & 6 section
CE Certficate number	:	V1 052126 0069 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	:	56675

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

EN ISO 13485:2016	Medical devices–Quality management systems–Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices.
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15197:2015	In vitro diagnosis test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 17511:2021	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
ISO 18113-1:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
ISO 18113-2:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

ISO 18113-3:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
ISO 18113-4:2022	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for self-testing
ISO 18113-5:2022	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 5: In vitro diagnostic instruments for self-testing
EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006+A1:2015	Medical device software – Software life cycle processes
EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for In vitro diagnostic (IVD) medical equipment.
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 301 489-1 V2.2.3:2019	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17 V3.2.2:2019	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 300 328 V2.2.2:2019	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

EN 62479:2010	Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
(EU) 2015/863	The restriction of the use of certain hazardous substances in electrical and electronic equipment.

2023. 8. 30

Date of Issue

Jim Jan

Jim Jan
Management Representative