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	:	Blood Glucose Monitoring System
Product model	:	TD-4183
Brand Name	:	Gluceofine Pro
Classification	:	98/79/EC (IVDD), Annex II, List B
Conformity Assessment Route	:	98/79/EC (IVD), Annex IV excluding section 4 & 6
EC Certificate 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	:	62537

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 diagnostic 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
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) - Part 4: 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 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101:2015	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 62304:2006+A1:2015	Medical device software - Software life cycle processes
EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
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
(EU) 2015/863	The restriction of the use of certain hazardous substances in electrical and electronic equipment.

2023. 9. 11

Date of Issue

Jim Jan

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Management Representative