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6樓
6F., No.127, Wugong 2nd Rd., Wugu Dist., New Taipei City 24888, Taiwan
Tel : +886-2-6625-8188
Fax : +886-2-6625-0288

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	: Blood Glucose Monitoring System :
Product Model	TD-4116
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.01
European Representative	: MedNet EC-REP GmbH Borkstraße 10, 48163 Münster , Germany
Notified Body (CE0123)	: TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany
GMDNS code	: 62537

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 15197:2015	In vitro diagnosis test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.
ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic instruments for professional use
EN ISO 18113-4:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing

Digitally signed by Moldoveanu Ruxanda
Date: 2021.12.15 12:22:15 EET
Reason: MoldSign Signature
Location: Moldova

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www.taidoc.com

EN ISO 18113-5:2011	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 ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
EN 13612:2002	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.
EN 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. General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
IEC 62304:2015	Medical device software -- Software life cycle processes [3] IEC/TR 8002-1 Medical device software – Part1 Guidance on application of ISO14971 to medical device software
ISO/IEC 12207:2008	Systems and software engineering -- Software life cycle processes
EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices

2021.10.27

Date of Issue

Jim Jan

Management Representative
Jim Jan