TaiDoc
泰博科技股份有限公司
TaiDoc Technology Corp.
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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	: 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.02
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) :

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 diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
EN 15223-1:2016	Medical devices - 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). In vitro diagnostic instruments for professional use
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). In vitro diagnostic reagents for self-testing

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Location: Moldova

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 device – 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. 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 - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006+A1:2015	Medical device software -- Software life cycle processes
ISO/IEC 12207:2008	Systems and software engineering- Software life cycle processes
EN 62366-1:2015	Medical devices -- Application of usability engineering to medical

2022. 1. 3.

Date of Issue

Jim Jan

Jim Jan

Management Representative