

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-4125
Classification	: 98/79/EC (IVDD), Annex II, List B
Conformity Assessment Route	: 98/79/EC (IVD), Annex IV excluding section 4&6 section
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 14971:2012	Medical devices - Application of risk management to medical devices
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements.
EN 62304:2006+A1:2015	Medical device software -- Software life cycle processes
EN ISO 15197:2015	In vitro diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
ISO 15223-1:2021	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). Terms, definitions and general requirements

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 18113-2:2011	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents 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
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 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 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 62366-1:2015	Medical devices -- Application of usability engineering to medical
(EU) 2015/863	The restriction of the use of certain hazardous substances in electrical and electronic equipment

2022.5.20

Date of Issue



**Jim Jan,
Management Representative**

Attachment to Declaration of Conformity 2022-05-20 – TD-4125

This attachment contains important additional information for the DoC to maintain its validity.

Updated information:

We declare under our sole responsibility that the product 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 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements.
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for In vitro diagnostic (IVD) medical equipment.
EN 62304:2006+A1:2015	Medical device software - Software life cycle processes
EN ISO 15197:2013	In vitro diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
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 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



www.taidoc.com

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B1-7樓
B1-7F., No.127, Wugong 2nd Rd., Wugu Dist.,
New Taipei City 24888, Taiwan

Tel : +886-2-6625-8188
Fax : +886-2-6625-0288

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 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.

2024-06-26, Taiwan

Date of Issue, Place of Issue

Jim Jan

Management representative