



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

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

www.tai.doc.com

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-4227
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.00
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 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
EN 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements



泰博科技股份有限公司
TaiDoc Technology Corp.

地址: 24858 板橋區五工一路127號5樓
6F-F, No.127, Wugong 2nd Rd, Wugu Dist.,
New Taipei City 24858, Taiwan

Tel : +886-2-6625-8186
Fax : +886-2-6625-0288

www.tai.doc.com

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 18113-3:2011	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	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 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 62366-1:2015	Medical devices -- Application of usability engineering to medical
EN 60601-1-6:2010+A1:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability
EN ISO 17511:2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances



泰博科技股份有限公司
TaiDoc Technology Corp.

新北市24688五股區五工三路127號51-2樓
51-2F, No.127, Wugong 3rd Rd, Wugu Dist.,
New Taipei City 24688, Taiwan

Tel : +886-2-6625-0100
Fax : +886-2-6625-0288

www.taiDoc.com

The object of the declaration described above is in conformity with Directive 98/79/EC, 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

2021.3.26

Date of Issue

Jim Jan

Jim Jan

Management Representative