TaiDoc
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, Wugu Dist., 24888 New Taipei City, TAIWAN

declare under our sole responsibility that the product

Product Name	:	Blood Glucose Test Strip
Product model	:	TD-4302
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	:	53307

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 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 medical device labels, labelling and information to be supplied. 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 18113-2:2011	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 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 / AC:2002	Performance evaluation of in vitro diagnostic medical devices

2022. 05. 24.

Date of Issue

Jim Jan

Jim Jan
Management Representative

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
www.taidoc.com

Attachment to Declaration of Conformity 2022-05-24 – TD-4302

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 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 18113-4:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents 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 / AC:2002	Performance evaluation of in vitro diagnostic medical devices

2024-08-06, Taiwan

Jim Jan

Date of Issue, Place of Issue

Jim Jan

Management epresentative