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

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-4365
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 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
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 18113-3:2022	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 ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
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 ISO 17511:2021	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials

2024-03-18

Date of Issue

Jim Jan
Management Representative