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, 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 0042 Rev.01
European Representative	: MedNet 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. 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 18113-4:2011	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). In vitro diagnostic instruments for self-testing
EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents

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Date: 2021.09.23 15:07:13 EEST
Reason: MoldSign Signature
Location: Moldova

EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
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

2019. 3. 11.

Date of Issue

Jim Jan

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Management Representative