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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 Control Solution
Product Model : TD-4907, TD-4908, TD-4909
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 (CE 0123) : TÜV SÜD Product Service GmbH
 Ridlerstraße 65, 80339 München, Germany
GMDN code : 41819

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



2023.11.02.

Date of Issue

Jim Jan
Management Representative