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	:	Lactate Test Strip
Product model	:	TD-4663
Classification	:	98/79/EC (IVDD), Annex II, Self-testing
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	:	53346

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 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). Terms, definitions and general requirements
ISO 18113-2:2022	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use
ISO 18113-4:2022	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 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
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

2023.12.28
Date of Issue

Jim Jan
Management Representative