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	: β- Ketone Control Solution
Product Model	: TD-4914, TD-4915
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 (CE 0123)	: TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany
GMDN code	: 53340

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 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples.
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-4:2011	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

2022. 5. 20.

Date of Issue

Jim Jan

Jim Jan

Management Representative