



# 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 control solution
- Product Model** : TD-4923, TD-4924
- 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** : 53344

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
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.
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



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

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

**2024.03.12.**

Date of Issue

**Jim Jan**

Management Representative