

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 0069 Rev.02
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 : 53307

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 ISO 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 18113-2:2011 | In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use |
| 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 23640:2015 | In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents |
| 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 |

2022.1.3.

Date of Issue



Jim Jan

Management Representative