TaiDoc
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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 | : | Uric Acid Test Strip |
| Product Model | : | TD-4653 |
| 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<br>Borkstraße 10, 48163 Münster , Germany |
| Notified Body (CE0123) | : | TÜV SÜD Product Service GmbH<br>Ridlerstraße 65, 80339 München, Germany |
| GMDNS code | : | 53586 |

**to which this declaration relates is in conformity with the following standard(s) or other normative document(s)：**

| Standard | Title |
|---|---|
| EN ISO 14971:2012 | Medical devices – Application of risk management to medical devices |
| EN ISO 23640:2015 | In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents |
| 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 18113-4:2011 | In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling)In vitro diagnostic reagents for self-testing |
| EN ISO 18113-5:2011 | In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic instruments for self-testing. In vitro diagnostic instruments for self-testing. |
| EN ISO 15223-1:2021 | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements |

| | |
|---|---|
| EN ISO 13485:2016 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| 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 — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples. |

2023 . 1 . 5

Date of Issue

Jim Jan

**Jim Jan**

Management Representative