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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, 24888 Wugu Dist, New Taipei City, TAIWAN

declare under our sole responsibility that the product

Product Name : Probe Cover
Product Model : TD-5507
Classification : 93/42/EEC(Directive including 2007/47/EC)(MDD), Annex IX, Rule 5, Class I
Conformity Assessment Route : 93/42/EEC(Directive including 2007/47/EC) (MDD), Annex VII (cfr. Article 11 paragraph 5)
European Representative : MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster , Germany
GMDN code : 13116- Covers, Thermometer Probe

| | |
|---------------------|--|
| 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 15223-1:2016 | Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1:General requirements |
| EN 62366-1:2015 | Medical devices - Application of usability engineering to medical devices |
| ISO 10993-1: 2018 | Biological evaluation of medical devices. Evaluation and testing within a risk management process |
| ISO 10993-12:2007 | Biological evaluation of medical devices. Sample preparation and reference materials |
| ISO 10993-5:2009 | Biological evaluation of medical devices. Tests for in vitro cytotoxicity |
| ISO 10993-10:2010 | Biological evaluation of medical devices. Tests for irritation and delayed-type hypersensitivity |



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We, TaiDoc declare that the above product of Class I is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.5 of the Directive, relating to the "EC Declaration of Conformity" set out in Annex VII.

2020.3.5.

Date of Issue

Jim Jan

Jim Jan

Management Representative