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
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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	: Sterile Blood Lancet
Product Model	: TD-5084
Classification	: 93/42/EEC(Directive including 2007/47/EC)(MDD), Annex IX, Section 2, Rule 6, Class IIa
Conformity Assessment Route	: 93/42/EEC(Directive including 2007/47/EC)(MDD) Annex II excluding (4)
EC Certificate Number	: G1 052126 0043 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	: 45142

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.
ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices-Part 11:tests for systemic toxicity.
ISO 10993-12:2021	Biological evaluation of medical devices. Sample preparation and reference materials

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ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation
ISO 11737-1:2018/Amd 1:2021	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11737-2:2019	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11137-1:2006/Amd 2:2018	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013/Amd 1:2022	Sterilization of health care products Radiation Part 2: Establishing the sterilization dose
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 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices

2024-05-02

Date of Issue

Jim Jan

Jim Jan
Management Representative