TaiDoc
泰博科技股份有限公司
TaiDoc Technology Corp.
www.taidoc.com

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):

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 10993-10:2010	Biological evaluation of medical devices. Tests for irritation and skin sensitization
ISO 10993-12:2012	Biological evaluation of medical devices. Sample preparation and reference materials
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

EN ISO 11607-1:2009+A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006+A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part1: Determination of population of microorganisms on products.
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN 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 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN 556-1:2001/AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 556-2:2015	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices

Digitally signed by Zagareanu Tatiana
Date: 2023.03.03 09:48:17 EET
Reason: MoldSign Signature
Location: Moldova

2022. 4. 11

Date of Issue

Jim Jan

Management Representative

Jim Jan