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
Fax : +886-2-6625-0288
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	: Ultrasonic Nebulizer
Product Model	: TD-7001
Classification	: 93/42/EEC (Directive including 2007/47/EC)(MDD), Annex IX, Section 3, Rule 11, 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.02
European Representative	: MedNet GmbH Borkstraße 10, 48163 Münster , Germany
Notified Body (CE0123)	: TÜV SÜD Product Service GmbH Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany
UMDNS code	: 35457

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 14971:2012	Medical devices - Application of risk management to medical devices.
EN 60601-1:2006+AC:2010	Medical electrical equipment - Part 1: General requirements for safety.
EN 60601-1-2:2007/AC:2010	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
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 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices.
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing

TaiDoc
www.taidoc.com
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
Fax : +886-2-6625-0288

ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1
ISO 10993-12:2012	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
EN 13544-1:2007+A1:2009	Respiratory therapy equipment - Part 1: Nebulizing systems and their components
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-11:2015	Medical electrical equipment –Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ISO 27427:2013	Anaesthetic and respiratory equipment – Nebulizing systems and components
EN 62366:2015	Medical devices —Application of usability engineering to medical devices.

2019. 11. 27

Date of Issue

Jim Jan

Jim Jan

Management Representative