TaiDoc
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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	: Blood Pressure Cuff
Product Model	: TD-3000
Basic UDI-DI	: 04698708300000T4
Classification	: 2017/745 (MDR), Annex VIII, Chapter III, Rule 1, Class I
Conformity Assessment Route	: 2017/745 (MDR), Annex IV (Annex II & III) (cfr. Article 52 paragraph 7)
European Representative	: MedNet EC-REP GmbH Borkstraße 10, 48163 Münster , Germany
GMDN code	: 34978

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

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. General requirements
EN 1041:2008_A1:2013	Information supplied by the manufacturer of medical devices
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro Cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: sample preparation and reference materials.

The above product of Class I is in conformity with the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017, and has been subject to the conformity assessment procedure laid down in Article 52 of the Regulation, relating to the "EC Declaration of Conformity" set out in Annex IV.

2021. 7. 13

Date of Issue

Jim Jan

Jim Jan

Management Representative