TaiDoc
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EC Declaration of Conformity

This Declaration of conformity is issued under the sole responsibility of the manufacturer.

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

Brand Name	:	TERUMO MEDISAFE FINETOUCH II
Product Name	:	Lancing Device
Product Model	:	TD-5016A (MS*FT2R), TD-5016B (MS*FT2S)
Basic UDI-DI	:	04698700500000PN
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	:	37243

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.
ISO 14971:2019	Medical devices -Application of risk management to medical devices.
EN ISO 15223-1:2021	Medical devices -Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1 :General requirements
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer

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. 11. 19.

Date of Issue

Jim Jan

Jim Jan
Management Representative