Body Clock Health Care Limited
108 George Lane
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sales@bodyclock.co.uk
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EC DECLARATION OF CONFORMITY

We, the Manufacturer, declare, in sole responsibility that the following products:

Product Type	Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief
Product and unique code	Elle TENS (D-BC04T) Elle TENS Plus (D-BC09T) Elle TENS 2 (D-BC138T) Smart TENS (D-BC05T)
Type Designation:	Class IIa Medical Device (TENS), Rule 9 Annex IX

is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC and is in conformity with the national standards transposing harmonised standards

EN ISO 14971:2012	Medical Device- Application of risk management to medical device.
EN 60601-1:2006+A12:2014	Medical electrical equipment – Part 1: General requirements for safety
EN 60601-1-2:2015	Medical electrical equipment – Collateral Standard – Part 1-2: Electromagnetic Compatibility
EN 60601-1-6: 2010+A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 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
EN 60601-2-10:2015+A1:2016	Medical electrical equipment – Particular requirements for the safety of nerve and muscle stimulators
EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices
EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes

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EN ISO 14155 : 2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 10993-1 : 2009 AC:2010	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5 : 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro
EN ISO 10993-10 : 2013	Biological Evaluation of medical devices. Tests for irritation and skin sensitization
ISO 15223-1 : 2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
Directive 2011/65/EU	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

and conforms to procedure set out in Annex Vof Directive 93/42/EEC under the supervision of Notified Body 1639 SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium under certificate no. GB19/964595, expiration 2023-04-06.

15th February 2021, London

Date and place of Declaration

Mrs Marilyn Bash
Managing Director

Registered in England
No. 2450177