



EC DECLARATION OF CONFORMITY

**Issued according to Annex II
to the Directive 93/42/EEC on Medical Devices
as amended by the Directive 2007/47/EC**

Manufacturer: BTL Industries Limited
161 Cleveland Way
Stevenage
SG1 6BU, Hertfordshire
United Kingdom

The **BTL Industries Limited** issues this Declaration of Conformity under its sole responsibility and herewith declares that the products

Product Description:	Combined Therapy Devices
Product Name:	BTL-4000 Smart BTL-4000 Premium
Product Models:	BTL-4820S Smart BTL-4820S Premium BTL-4825S Smart BTL-4825S Premium BTL-4820L Smart BTL-4820L Premium BTL-4825L Smart BTL-4825L Premium BTL-4800SL Smart BTL-4800SL Premium BTL-4820SL Smart BTL-4820SL Premium BTL-4825SL Smart BTL-4825SL Premium BTL-4800LM2 Smart BTL-4800LM2 Premium BTL-4820M2 Smart BTL-4820M2 Premium BTL-4825M2 Smart BTL-4825M2 Premium BTL-4820M4 Smart BTL-4820M4 Premium BTL-4825M4 Smart BTL-4825M4 Premium BTL-4820LM2 Smart BTL-4820LM2 Premium BTL-4825LM2 Smart BTL-4825LM2 Premium

Product Description:	Electrotherapy Devices
Product Name:	BTL-4000 Smart BTL-4000 Premium

Product Models:	BTL-4620 Smart BTL-4620 Premium BTL-4625 Smart BTL-4625 Premium
Product Description:	Ultrasound Therapy Devices
Product Name:	BTL-4000 Smart BTL-4000 Premium
Product Models:	BTL-4710 Smart BTL-4710 Premium
Product Description:	Laser Therapy Devices
Product Name:	BTL-4000 Smart BTL-4000 Premium
Product Models:	BTL-4110 Smart BTL-4110 Premium
Product Description:	Magnetotherapy Devices
Product Name:	BTL-4000 Smart BTL-4000 Premium
Product Models:	BTL-4920 Smart BTL-4920 Premium BTL-4940 Smart BTL-4940 Premium
Risk Classification:	Class IIb According to Annex IX of MDD

are in conformity with requirements of Annex I to the Directive 93/42/EEC on Medical Devices as amended by the Directive 2007/47/EC

and bear the CE mark:



Notified Body:	DNV GL Nemko Presafe, AS
EC Certificate No.:	10414-2017-CE-CZS-NA-PS

Date of Issue: July 12, 2018
Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

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Regulatory Affairs