



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

Authorised Representative:

BTL ITALIA S.r.l.
Via San Leonardo 120
84131, Salerno
Italy

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 Product Assurance AS

EC Certificate No.:

10414-2017-CE-CZS-NA-PS

Date of Issue: May 24, 2021

Signature on behalf of BTL Industries Ltd.

Place of Issue: **Stevenage**

BTL Industries Limited
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United Kingdom

Jakub Machalek
Regulatory Affairs Manager