



## 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:	<b>BTL-4620 Smart BTL-4620 Premium BTL-4625 Smart BTL-4625 Premium</b>
Product Description:	<b>Ultrasound Therapy Devices</b>
Product Name:	<b>BTL-4000 Smart BTL-4000 Premium</b>
Product Models:	<b>BTL-4710 Smart BTL-4710 Premium</b>
Product Description:	<b>Laser Therapy Devices</b>
Product Name:	<b>BTL-4000 Smart BTL-4000 Premium</b>
Product Models:	<b>BTL-4110 Smart BTL-4110 Premium</b>
Product Description:	<b>Magnetotherapy Devices</b>
Product Name:	<b>BTL-4000 Smart BTL-4000 Premium</b>
Product Models:	<b>BTL-4920 Smart BTL-4920 Premium BTL-4940 Smart BTL-4940 Premium</b>
Risk Classification:	<b>Class IIb</b> 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:	<b>DNV GL Nemko Presafe, AS</b>
EC Certificate No.:	<b>10414-2017-CE-CZS-NA-PS</b>

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

Signature on behalf of BTL Industries Ltd.

**BTL Industries Limited**  
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**Daniel Tokar**  
Regulatory Affairs