



## 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 Device**

**Product Name:**

**BTL-5000 Series / BTL-5000 Combi**

**Product Models:**

**BTL-5820S (BTL-5820S Combi)  
BTL-5825S (BTL-5825S Combi)  
BTL-5820SL (BTL-5820SL Combi)  
BTL-5825SL (BTL-5825SL Combi)  
BTL-5816SLM (BTL-5816SLM Combi)  
BTL-5818SLM (BTL-5818SLM Combi)  
BTL-5825L (BTL-5825L Combi)  
BTL-5825M2 (BTL-5825M2 Combi)  
BTL-5800SL (BTL-5800SL Combi)  
BTL-5800LM2 (BTL-5800LM2 Combi)**

**Product Description:**

**Electrotherapy Device**

**Product Name:**

**BTL-5000 Series / BTL-5000 Puls**

**Product Models:**

**BTL-5620 Puls  
BTL-5625 Puls  
BTL-5640 Puls  
BTL-5645 Puls**

**Product Description:**

**Ultrasound Therapy Device**

**Product Name:**

**BTL-5000 Series / BTL-5000 Sono**

**Product Models:**

**BTL-5710 Sono  
BTL-5720 Sono**

**Product Description:**

**Laser Therapy Device**

**Product Name:**

**BTL-5000 Series / BTL-5000 Laser**

**Product Models:**

**BTL-5110 Laser**

**Product Description:**

**Magnetotherapy Device**

**Product Name:**

**BTL-5000 Series / BTL-5000 Magnet**

**Product Models:**

**BTL-5920 Magnet  
BTL-5940 Magnet**



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.:

10416-2017-CE-CZS-NA-PS Rev. 0.0

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Date of Issue: April 30, 2018  
Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

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

**Daniel Tokar**  
Regulatory Affairs