BTL Industries

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 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**

Digitally signed by Zagareanu Tatiana
Date: 2024.07.12 11:09:59 EEST
Reason: MoldSign Signature
Location: Moldova

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
BTL MEDICAL TECHNOLOGIES
IDNO 1022600046052, mun. CHIȘINĂU
REPUBLICA MOLDOVA

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:	CE 2460
Notified Body:	DNV Product Assurance AS
EC Certificate No.:	10416-2017-CE-CZS-NA-PS

Date of Issue: May 24, 2021
Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited
Elder Gate, 9 Way
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United Kingdom

Jakub Machalek
Regulatory Affairs Manager

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