EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10416-2017-CE-CZS-NA-PS Rev. 0.0	**PRJC-88820-2008-PRC-CZE**	**14 April 2023**

This is to certify that the quality system of:

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

For design, production and final product inspection/testing of:

Electromedical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 26 April 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No. 2460

Digitally signed by Moldoveanu Ruxanda
Date: 2020.02.26 14:58:36 EET
Reason: MoldSign Signature
Location: Moldova

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	**Supersedes DNV GL (NB0434) certificate No. 23005-2008-CE-NOR 8.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460) Recertification**	**26-04-2018**

Products covered by this certificate:

Product Description	Product Name	Class
Combined Therapy Devices	BTL-5000 Series / BTL-5000 Combi • 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)	IIb
Electrotherapy Devices	BTL-5000 Series / BTL-5000 Puls • BTL-5620 Puls • BTL-5625 Puls • BTL-5640 Puls • BTL-5645 Puls	IIb
Ultrasound Therapy Devices	BTL-5000 Series / BTL-5000 Sono • BTL-5710 Sono • BTL-5720 Sono	IIb
Laser Therapy Devices	BTL-5000 Series / BTL-5000 Laser • BTL-5110 Laser	IIb
Magnetotherapy Devices	BTL-5000 Series / BTL-5000 Magnet • BTL-5920 Magnet • BTL-5940 Magnet	IIb

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The complete list of devices is filed with the Notified Body

Sites covered by this certificate:

Site Name	Address
BTL Industries JSC	30 Peshtersko shouse blvd., 4002, Plovdiv, Bulgaria
Medical Technologies CZ a.s.	Evropská 423/178, 160 00 Prague 6, Czech Republic

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate