EC Certificate
Full Quality Assurance System

Certificate No.:
10414-2017-CE-CZS-NA-PS

Project No.:
PRJC-88820-2008-PRC-CZE

Valid Until:
26 July 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 Annex II excluding section 4 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, 11 July 2018

Digitally signed by Zagareanu Tatiana
Date: 2023.12.15 09:27:37 EET
Reason: MoldSign Signature
Location: Moldova

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Mariann Jeremiassen
Management Representative

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

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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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
	Recertification. Supersedes DNV GL Nemko Presafe AS (NB2460) certificate no. 12583-2018-CE-CZS-NA-PS	**2018-07-26**

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Certificate No.: **10414-2017-CE-CZS-NA-PS**

Project No.: **PRJC-88820-2008-PRC-CZE**

Valid Until: **26 July 2023**

Products covered by this Certificate:

Product Description	Product Name	Class
Combined Therapy Devices	BTL-4000 Smart BTL-4000 Premium • 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	IIb
Combined Therapy Devices	BTL-4000 Smart BTL-4000 Premium • BTL-4820LM2 Smart • BTL-4820LM2 Premium • BTL-4825LM2 Smart • BTL-4825LM2 Premium	IIb
Electrotherapy Devices	BTL-4000 Smart BTL-4000 Premium • BTL-4620 Smart • BTL-4620 Premium • BTL-4625 Smart • BTL-4625 Premium	IIb
Ultrasound Therapy Devices	BTL-4000 Smart BTL-4000 Premium	IIb

	• BTL-4710 Smart • BTL-4710 Premium	
Laser Therapy Devices	BTL-4000 Smart BTL-4000 Premium • BTL-4110 Smart • BTL-4110 Premium	IIb
Magnetotherapy Devices	BTL-4000 Smart BTL-4000 Premium • BTL-4920 Smart • BTL-4920 Premium • BTL-4940 Smart • BTL-4940 Premium	IIb
Vacuum Unit for Electrotherapy	BTL-Vac II	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this Certificate:

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

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