EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid until:
10251-2017-CE-CZS-NA-PS Rev 0.0	PRJC-88820-2008-PRC-CZE	14 July 2022

This is to certify that the quality system of:

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

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

Software application for cardiology field

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) 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, 14 July 2017

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård

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 for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0	**Supersedes DNV GL (NB0434) certificate No. 112965-2012-CE-CZS-NA 2.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460) Recertification**	**2017-07-14**

Products covered by this Certificate:

Product Description	Product Name	Class
Software application for unified cardiology field	BTL CardioPoint • BTL CardioPoint–Holter • BTL CardioPoint–Ergo • BTL CardioPoint –Stress • BTL CardioPoint–ECG • BTL CardioPoint–Spiro • BTL CardioPoint–ABPM	IIa
	MEW (second name of the same product) • MEW–Holter • MEW–Ergo • MEW–Stress • MEW–ECG • MEW–Spiro • MEW–ABPM	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

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