

BTL Industries Limited

161 Cleveland Way Stevenage Hertfordshire SG1 6BU UNITED KINGDOM

UL LLC[®](UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016 EN ISO 13485:2016

Design, development, production, sales and service of therapeutic, diagnostic and cardiology devices such as: diathermy, microwave, heat and cold therapy devices, high intensity magnet, passive motion, traction units, shockwave and acoustic wave, high frequency, hydrotherapy, pulsed light, lymphatic drainage devices, therapeutic laser, ultrasound, electrotherapy, vacuum units and magnetic therapy devices and their combinations; ambulatory blood pressure monitors, spirometry and other pulmonary function test equipment, cardiology recorders and software for diagnostics, all related accessories for the devices; sterile high frequency therapeutic devices and accessories; therapy beds and gynaecological/urological chairs.

Certificate with Addendum(s) totals 3 pages.



Authorized by

Paul Hilgeman Director & Global Industry Leader, Medical CMIT – Medical Regulatory

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Check Certificate Status: <u>here</u>

File Number	A28507
Certificate Number	1427.220409
Initial Issue Date	April 9, 2018

Cycle Start April 9, 2021 Effective Date April 9, 2022 Expiry Date April 8, 2024

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



UL LLC 333 Pfingsten Road Northbrook, IL 60062-2096 USA



BTL Industries Limited

161 Cleveland Way Stevenage Hertfordshire SG1 6BU UNITED KINGDOM

Addendum 1 1-1 BTL Industries Limited 161 Cleveland Way Stevenage Hertfordshire SG1 6BU UNITED KINGDOM Performing: Mailing address only.

2-1

BTL Industries JSC
30 Peshtersko Shose Blvd.
4002 Plovdiv BULGARIA
Performing: Manufacturing, purchasing, sales, distribution, service, human resources.

3-1

BTL Industries JSC 45 Bregalnitsa 1303 Sofia BULGARIA Performing: Design and development.

4-1

BTL Medical Technologies s. r. o. / BTL Healthcare Technologies a.s.
Evropska 423/178
160 00 Prague CZECH REPUBLIC
Performing: Design and development, CAPA, customer complaints, market surveillance and regulatory affairs.

5-1
BTL Industries JSC
17 Kuklensko shose blvd.
4004 Plovdiv BULGARIA
Performing: Metal processing, production of metal parts/sub-assemblies.

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Form-ULID-000724 Issue 3.0



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Addendum 2 5-2 BTL Industries JSC 11 Kuklensko shose blvd. 4004 Plovdiv BULGARIA Performing: Labeling, final inspection, storage, sales and distribution.

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