CERTIFICATE OF REGISTRATION



BTL Industries Limited

161 Cleveland Way Stevenage

Hertfordshire SG1 6BU UNITED KINGDOM

Tên chủ sở hữu & nhà sản xuất (1) sản phâm

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 Địa chỉ chủ sở hữu & nhà sản xuất (1) sản phẩm

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.



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

Authorized by

Check Certificate Status: here

File Number A28507 Certificate Number 1427.220409 Effective Date April 9, 2022 Initial Issue Date April 9, 2018

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

> Ngày hết hiệu lực: 08/04/2024



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

Cycle Start April 9, 2021

Expiry Date April 8, 2024

CERTIFICATE OF REGISTRATION



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

Tên nhà sản xuất (2) sản phẩm

BTL Industries JSC

30 Peshtersko Shose Blvd.

4002 Plovdiv BULGARIA

Performing: Manufacturing, purchasing, sales, distribution, service, human resources.

3-1

Địa chỉ nhà sản xuất (2) sản phẩm

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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Ngày hết hiệu lực: 08/04/2024

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CERTIFICATE OF REGISTRATION



BTL Industries Limited

161 Cleveland Way Stevenage Hertfordshire SG1 6BU UNITED KINGDOM

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

File Number A28507 Cycle Start April 9, 2021
Certificate Number 1427.220409 Effective Date April 9, 2022
Initial Issue Date April 9, 2018 Expiry Date April 8, 2024

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