



BTL Industries

EC DECLARATION OF CONFORMITY

**Issued according to Annex II
to the Directive 93/42/EEC on Medical Devices
as amended by the Directive 2007/47/EC**

Manufacturer:

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

The **BTL Industries Limited** herewith declares under its sole responsibility that the product

Product Name:

BTL-6000 Lymphastim

Product Models:

BTL-6000 Lymphastim 6 Easy
BTL-6000 Lymphastim 12 Easy
BTL-6000 Lymphastim 12 Topline

Product Description:

Lymphatic Pressure Unit / Lymphatic Drainage

Risk Classification:

Class IIa
According to Annex IX of MDD

is in conformity with requirements of Annex I to the Directive 93/42/EEC on Medical Devices as amended by the Directive 2007/47/EC

and bears the CE mark:



Notified Body:

DNV GL Nemko Presafe, AS

EC Certificate No.:

10418-2017-CE-CZS-NA-PS Rev. 0.0

Date of Issue: April 30, 2018

Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited

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Regulatory Affairs