

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 Shortwave**
Product Models: **BTL-6000 Shortwave 200**
BTL-6000 Shortwave 400
Product Description: **Shortwave Diathermy Device**
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.: **10417-2017-CE-CZS-NA-PS Rev. 0.0**

Date of Issue: **April 27, 2018**
Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited
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Daniel Tokar
Regulatory Affairs