

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 Ltd.
161 Cleveland Way
Stevenage
Hertfordshire SG1 6BU
United Kingdom

Authorised representative:

BTL ITALIA S.r.l.
Via San Leonardo 120
84131, Salerno
Italy

The **BTL Industries Limited** issues this Declaration of Conformity under its sole responsibility and herewith declares that the product:

Product Description:

Focused Shockwave Therapy Device

Product Name:

BTL-6000 FSWT

Risk Classification:

Class IIb
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 Product Assurance AS

EC Certificate No.:

10000418361-PA-NA-CZE

Date of Issue: May 21, 2021

Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited
161 Cleveland Way
Stevenage
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Jakub Machalek
Regulatory Affairs Manager