

# 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** issues this Declaration of Conformity under its sole responsibility and herewith declares that the product

Product Name: **BTL-6000 X-Wave Optimal**

Product Description: **Shockwave Therapy 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.: **11259-2017-CE-CZS-NA-PS Rev. 0.0**

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Date of Issue: **April 26, 2018**  
Place of issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

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

**Daniel Tokar**  
Regulatory Affairs