

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

Authorised Representative:

BTL ITALIA S.r.l.
Via Delle Rimembranze, 10 (Linate)
20068, Peschiera Borromeo (MI)
Italy

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

Product Name:

BTL-6000 Super Inductive System

Product Model:

BTL-6000 Super Inductive System Elite

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

Date of Issue: December 15, 2020

Place of Issue: Stevenage

Signature on behalf of BTL Industries Ltd.

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

Jakub Machalek
Regulatory Affairs