

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
and according to Annex VIII to the Directive 2006/42/EC on Machinery**

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 Description: **Continuous Passive Motion Device**

Product Name: **BTL-CPMotion**

Product Models: **BTL-CPMotion K EASY
BTL-CPMotion K PRO
BTL-CPMotion K 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 in conformity with requirements of Annex I to the Directive 2006/42/EC.

and bears the CE mark:



Notified Body: **DNV GL PRESAFE, AS**

EC Certificate No.: **10409-2017-CE-CZS-NA-PS**

Date of Issue: **2nd March, 2020**

Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited
161 Cleveland Way
Stevenage
SG1 6BU Hertfordshire
United Kingdom
Lukas Mnozil
Head of Regulatory Affairs