



BTL Industries

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-08 Spiro**

Product Description: **Spirometer**

Risk Classification: **Class IIa**
According to Annex IX of MDD

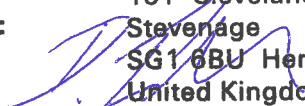
is in conformity with requirements of Annex I to the Directive 93/42/EEC on Medical Devices as amended by the Directive 2007/47/EC

and bears the CE mark:



Notified Body: **DNV GL Nemko Presafe, AS**

Date of Issue: **July 18, 2017**
Place of Issue: **Stevenage**

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

Daniel Tokar
Regulatory Affairs