



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 Pro**

Product Description: **Spirometer**

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

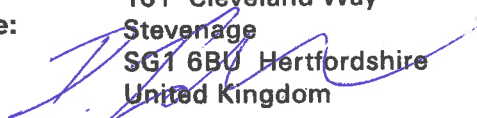
is in conformity with requirements of Annex I to the Directive 93/42/EEC on Medical Devices as amended by the Directive 2007/47/EC

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