

# 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**