



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 Holter**

Product Models: **BTL-08 Holter H100**  
**BTL-08 Holter H300**  
**BTL-08 Holter H600**

Product Description: **Ambulatory ECG Holter monitor**

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**

EC Certificate No.: **11256-2017-CE-CZS-NA-PS Rev. 0.0**

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Date of Issue: **May 4, 2018**  
Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

**BTL Industries Limited**  
161 Cleveland Way  
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SG1 6BU Hertfordshire  
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**Daniel Tokar**  
Regulatory Affairs