

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

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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Daniel Tokar
Regulatory Affairs