

# 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 products

Product Names: **BTL-08 SD**  
**BTL-08 MT Plus**  
**BTL-08 LC**  
**BTL-08 LT**

Product Models: **BTL-08 SD1**  
**BTL-08 SD3**  
**BTL-08 SD6**  
**BTL-08 MT Plus**  
**BTL-08 LC**  
**BTL-08 LC Plus**  
**BTL-08 LT**  
**BTL-08 LT Plus**

Products Description: **Electrocardiograph**

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

are 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 bear the CE mark:



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

EC Certificate No.: **11253-2017-CE-CZS-NA-PS Rev. 0.0**

Date of Issue: **April 30, 2018**  
Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

**BTL Industries Limited**  
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**Daniel Tokar**  
Regulatory Affairs