

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