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
and according to Annex II and Annex VI
to the Directive 2014/53/EU on Radio equipment

Manufacturer:	**BTL Industries Limited** 161 Cleveland Way Stevenage SG1 6BU, Hertfordshire United Kingdom

The **BTL Industries Limited** issues this Declaration of Conformity under its sole responsibility and herewith declares that the product

Product Name:	**BTL Flexi 12 ECG**
Product Description:	**12 Channel Electrocardiograph system**
Product Types:	**BTL Flexi 12 ECG** **BTL CardioPoint Flexi**
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 in conformity with requirements of Article 3 of the Directive 2014/53/EU on Radio Equipment

and in conformity with the harmonized standards EN 60601-1:2006+A1:2013, EN 60601-1-2:2010, EN 60601-2-25:2015, EN 60601-1-6:2010+A1:2015, EN 62366:2008+A1:2015, EN 62304:2006, EN 62133:2013, EN 61960:2011 and ETSI EN 300 328 V2.1.1.

and bears the CE mark:	CE 1434
Notified Body:	Polskie Centrum Badań i Certyfikacji S.A.
EC Certificate No.:	1434-MDD-224/2019

Date of Issue: 29th April 2019
Place of Issue: **Stevenage**

Signed on behalf of BTL Industries Ltd.

BTL Industries Limited
161 Cleveland Way
Stevenage
SG1 6BU, Hertfordshire
United Kingdom

Daniel Tokar
Regulatory Affairs

Digitally signed by Moldoveanu Ruxanda
Date: 2020.07.31 11:18:53 EEST
Reason: MoldSign Signature
Location: Moldova