



CERTIFICATE

EC Certificate No. 1434-MDD-224/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

BTL Industries Limited

161 Cleveland Way, Stevenage
Hertfordshire SG1 6BU, United Kingdom

for the design, manufacture and final inspection of

medical devices, class IIa

12 channel electrocardiograph system
Model/Type: BTL Flexi 12 ECG, BTL CardioPoint Flexi

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from **25.04.2019** to **28.11.2022**

The date of issue of the Certificate: **25.04.2019**



Application No: **574/2019**
Module **H**


mgr Anna Wyroba
Vice-President



Certificate No. **1434-MDD-224/2019**
Issued under the Contract No. **MD-86/2019**
Bears the PCBC hologram
Warszawa, 25/04/2019