

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
11256-2017-CE-CZS-NA-PS Rev. 2.0

Project No.:  
PRJC-88820-2008-PRC-CZE

Valid Until:  
14 April 2023

This is to certify that the quality system of:

### **BTL Industries Limited**

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

For design, production and final product inspection/testing of:

### **ELECTROCARDIOGRAPH DEVICES – ECG HOLTER MONITOR**

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN  
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE  
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
Havik, 9 February 2021

For:  
**DNV GL PRESAFE AS**  
Notified Body No.: 2460

*Eugenie Winger Husebye*

**Eugenie Winger Husebye**

The certificate is digitally verified by blockchain technology. For more info, see  
[www.dnvgl.com/assurance/certificates/btl-blockchain.html](https://www.dnvgl.com/assurance/certificates/btl-blockchain.html)



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.  
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Havik, Norway - Registered Enterprise No: NO 997 067 521 HVA/DNV 10728004-2021