

EC CERTIFICATE

Full Quality Assurance System

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

Project No.:
PRC-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:
Høvik, 9 February 2021

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

Eugenie Winger Husebye

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The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificate/blockchain-technology



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 Høvik, Norway - Registered Enterprise No: NO 997 067 421 WVA (DNV 107280000)