EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland

Registration No.:	HZ 2036797-1
Manufacturer:	**BTL Industries Limited** 161 Cleveland Way SG1 6BU Stevenage, Hertfordshire United Kingdom
EUDAMED Single Registration No.:	N/A
Products:	Product of class IIa: - Z129082 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS – SOFTWARE ACCESSORIES - Z121501 - SPIROMETRY INSTRUMENTS - Z120504 - HOLTER SYSTEM INSTRUMENTS FOR CARDIOVASCULAR PARAMETERS - Z120503 - ELECTROCARDIOGRAPHS
Authorised representative(s):	BTL Italia S.r.l. Via Delle Rimembranze, 10 (Linate) 20068, Peschiera Borromeo (MI) Italy

Certificate history		
Revision:	Description:	Issue date:
1	Initial certification	2023-02-03

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	84957111-170
Effective date:	2023-02-03
Expiry date:	2027-08-28
Issue date:	2023-02-03

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

Jarosław Pyclik
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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Digitally signed by Zagaicanu Tatiana
Date: 2024.02.26 09:06:32 EET
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