BTL Industries

EU DECLARATION OF CONFORMITY

Issued in accordance with Annex IV of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, as amended (hereinafter Regulation (EU) 2017/745) and in accordance with other relevant Union legislation that provides for the issuing of an EU declaration of conformity

Manufacturer:

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

SRN: GB-MF-000034894

Authorised Representative:

BTL ITALIA S.r.l.
Via San Leonardo 120
84131, Salerno
Italy

SRN: IT-AR-000020508

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

Trade Name:

BTL CardioPoint
BTL CardioPoint-ABPM
BTL CardioPoint-Holter
BTL CardioPoint-Spiro
BTL CardioPoint-Stress
BTL CardioPoint-Ergo
BTL CardioPoint-ECG

Risk Class: **Class IIa**

Conformity procedure: **Annex IX, Chapters I and III**

Basic UDI-DI: **++B108590SWK6**

is in conformity with Regulation (EU) 2017/745 and other relevant Union legislation and bears the CE mark:

CE 0197

Notified Body: TÜV Rheinland LGA Products GmbH

EC Certificate No.: HZ 2036797-1

Date of Issue: **2023-04-17**
Place of Issue: **Stevenage**

Digitally signed by Zagareanu Tatiana
Date: 2024.02.26 09:06:39 EET
Reason: MoldSign Signature
Location: Moldova

Signature on behalf of BTL Industries Ltd.-

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

Jakub Machalek
Regulatory Affairs Manager

SOCIETATEA CU RASPUNDERE LIMITATA * S.R.L. BTL MEDICAL TECHNOLOGIES * IDNO 1022600048052 * REPUBLICA MOLDOVA, mun. CHIȘINĂU