

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-08 Spiro Pro
BTL-08 Spiro
BTL Pneumotachograph

Risk Class:

Class IIa

Conformity procedure:

Annex IX, Chapters I and III

Basic UDI-DI:

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



Notified Body:

TÜV Rheinland LGA Products GmbH

Certificate No.:

HZ 2036797-1

Date of Issue: 2023-04-17

Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

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

Jakub Machalek
Regulatory Affairs Manager