



BTL Industries

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** as manufacturer issues this EU Declaration of Conformity under its sole responsibility and herewith declares that the product

Trade Name: **BTL-Vac II**

Risk Class: **Class I**

Conformity procedure: **Annex II & Annex III**

Basic UDI-DI: **++B108042POVACEU5L**

Intended purpose: The BTL-Vac II vacuum unit as an accessory is intended for easy and convenient attachment of vacuum electrodes of electrotherapy devices to patient's body to perform electrotherapy.

is in conformity with: Regulation (EU) 2017/745 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

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended

and bears the CE mark:



Date of Issue: 2024/09/09
Place of Issue: **Stevenage**

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited
161 Cleveland Way
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United Kingdom

Jakub Machalek
Regulatory Affairs Manager