



BTL Industries

EC DECLARATION OF CONFORMITY

**Issued according to Annex II
to the Directive 93/42/EEC on Medical Devices
as amended by the Directive 2007/47/EC**

Manufacturer:

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

Authorised Representative:

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

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

Product Description:

High frequency and ultrasound device for the treatment of obesity, sexual dysfunctions and for dermatological procedures and related accessories

Micro-needle tips and superficial needles for radio-frequency dermatological treatment

Product Name:

BTL-785F

BTL-785-1; BTL-785-2; BTL-785-3; BTL-785-4; BTL-785-1-1; BTL-785-1-2; BTL-785-2-1; BTL-785-2-2; BTL-785-2-3; BTL-785-3-1; BTL-785-3-2; BTL-785-3-3

BTL-785-4-1; BTL-785-4-2; BTL-785-4-3; BTL-785-4-4; BTL-785-4-5; BTL-785-4-6; BTL-785-4-7; BTL-785-4-8

Risk Classification:

Class IIb

According to Annex IX of MDD

is in conformity with requirements of Annex I to the Directive 93/42/EEC on Medical Devices as amended by the Directive 2007/47/EC

and bears the CE mark:



Notified Body:

IMQ - Istituto Italiano del Marchio di Qualità S.p.A.

EC Certificate No.:

2005/MDD

Date of Issue: May 20, 2021

Place of Issue: **Stevenage**

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