



BTL Industries

DECLARATION OF CONFORMITY

for CE – marking according to Annex II
of Medical Devices Directive 93/42/EEC

Manufacturer:

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

The BTL Industries Ltd. herewith declares under its sole responsibility that the product

Product Name:
Type:

Product Name:
Type:

Product Name:
Type:

Product Name:
Type:

Product Name:
Type:

Product Name:
Type:

Combined therapy devices
BTL-5000 Series vLxx
BTL-4000 Series vLxx
Electrotherapy devices
BTL-06 v3xx
BTL-5000 Puls vLxx
BTL-4000 Puls vLxx
Vacuum devices
BTL-12 v2xx
BTL vac vLxx
Ultrasound therapy devices
BTL-07p v4xx
BTL-5000 Sono vLxx
BTL-4000 Sono vLxx
Laser therapy devices
BTL-10 v5xx
BTL-2000 v5xx
BTL-5000 Laser vLxx
BTL-4000 Laser vLxx
Magnetotherapy devices
BTL-09 v4xx
BTL-5000 Magnet vLxx
BTL-4000 Magnet vLxx

Risk Classification:

Class IIb

conforms with the applicable regulation:
Directive:

MDD 93/42/EEC

Quality Assurance Standards:

ISO 13485 : 2003

Procedural Standards:

EN 60601-1 + A2, EN 60601-1
EN 60601-2-1, EN 60601-2-10
EN 60601-2-5, EN 60601-2-22
EN 60825-1, EN ISO 14971, ISO 10993-1

Date of Issue: 26th January 2006
Place of Issue: Hertfordshire

Signature:

Daniela Marx
Director of BTL Industries Limited