



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:

BTL-5000 SWT

Type:

**BTL-5000 SWT Power
BTL-5000 SWT Basic**

Risk Classification:

Class IIb

is in conformity with applicable regulation:

Directive:

MDD 93/42/EEC

Quality Assurance Standards:

**EN ISO 9001: 2000
ISO 13485:2003**

Procedural Standards:

**EN 60601-1:1990
EN 60601-1/A1:1993
EN 60601-1/A2:1995
EN 60601-1:2001
EN 60601-2: 2001
EN 60601-4:1996
EN 60601-4/A1:1999
EN ISO 14971:2007
ISO 10993-1:1996
EN ISO 14155-1:2003**

Date of Issue: **1st May 2008**

Place of Issue: **Stevenage**

Signature:

Filip Donner

Product manager of BTL Industries Limited