



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:

Ambulatory Blood Pressure Monitor

Type:

BTL-08 ABPM

Risk Classification:

Class IIa

Confirms with the 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 60601-1-2:2001
EN 60601-2: 2001
EN 60601-4:1996
EN 60601-4/A1:1999
EN 60601-2-30:2001
EN ISO 14971:2003
EN ISO 10993:1996**

Date of Issue: **8th December 2008**

Place of Issue: **Stevenage**

Signature:

Philip Donner

Product manager of BTL Industries Limited