



BTL Industries

DECLARATION OF CONFORMITY

for CE – marking according to Annex II
of Medical Devices Directive 93/42/EEC
as amended 2007/47/ES

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 products

Product Name:

BTL-08 ECG

Type:

**BTL-08 S ECG
BTL-08 SD ECG
BTL-08 MD ECG
BTL-08 MT Plus ECG
BTL-08 LT ECG
BTL-08 LC ECG**

Risk Classification:

Class IIa

Confirm with the applicable regulation:

Directive:

**MDD 93/42/EEC:1993
MDD 2007/47/ES**

Quality Assurance Standards:

**EN ISO 9001:2008
ISO 13485:2003**

Procedural Standards:

**EN 60601-1:1990
EN 60601-1/A1:1993
EN 60601-1/A2:1995
EN 60601-1-1:2001
EN 60601-1-2: 2001
EN 60601-1-4:1996
EN 60601-1-4/A1:1999
EN 60601-2-25:1995
EN 60601-2-25/A1:1999
EN 60601-2-51:2003
EN ISO 14155-1:2003
EN ISO 14971:2000
ISO 10993-1:1996**

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Signature:

Ivan Jacko

Quality manager of BTL Industries Limited