Page 88 Appendix

## 9.2 EC declaration of Conformity

## EC declaration of Conformity

Document No. / Month. Year: QKE 15.00.002-14 / 02.05

Manufacturer: Medset Medizintechnik GmbH

Curslacker Neuer Deich 66

D-21029 Hamburg

We hereby declare that the product:

Holter-ECG-System CARDIOLIGHT

consisting of:

Holter ECG Recorders with Holter ECG software

CARDIOLIGHT from Version 3.5a

from Version A in the following models:

in the following models: Economy, Sirius, Antares, Planet

**SMART** 

from Version A

TELESMART-H

in the following models: PR, SR, SR-3, SR-PD, SR-PD-3

with the following accessories recorder bag, TELESMART

patient cable, TELESMART

recorder bag, SMART patient cable, SMART

recorder opto-interface cable, SMART

complies with European Directive 93/42/EEC of the Council of 14th June 1993 concerning medical products.

It bears the mark:

**C € 0124** 

Hamburg, 28th February 2005

Medset Medizintechnik GmbH

Legally binding signature:

Klaus Kophstahl

- CEO -

CARDIOLIGHT - Holter ECG Evaluation System for PADSY from Version 3.5b

The technical documentation is kept in quality department.