PLOHLA'SENT O SHOD,



Manufacturer's Name: Manufacturer's Address:

Hewlett-Packard Company 3000 Minuteman Road Andover, Ma. 01810 USA

declares, that the product

Electrocardiograph

Product Name:

PageWriter

Model Number(s):

M1770A, starting with date: 1/Dec/98 M1771A, starting with date: 1/Dec/98 M1772A, starting with date: 1/Dec/98

Product Options/Revisions (as described in the attached list) All options and accessories as defined in the User's Guide (M1770-91930) and Technical Data Sheet (5968-1039E)

to which this declaration relates is in conformity with the European Directive (MDD):

93/42/EEC

"Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices"

The technical documentation and full compliance with the standard(s) or other normative document(s) listed below proves the conformity with the essential requirements of the above-mentioned EC Directive :

Safety, Performance:

IEC 601-1:1988 + A2, EN60601-1:1990.

IEC 601-2-25:1993

EMC:

IEC 601-1-2:1993

Conducted Emission: CISPR 11:1990, EN60601-1-2:1993, Class A Radiated Emission: CISPR 11:1990, EN60601-1-2:1993, Class A

ESD: IEC 801-2:1991, EN60601-1-2:1993

Radiated Immunity: EN61000-4-3:1996, EN60601-1-2:1993

Fast Transients/Bursts: IEC 801-4:1988, EN60601-1-2:1993

Surges: EN61000-4-5:1995, EN60601-1-2:1993

Supplementary Information:

Hewlett Packard Andover is certified according to Annex II Section 3.2 of the MDD, issued by TUV-PS under EN46001

The product was tested in a typical configuration of a Hewlett-Packard electrocardiograph as described in the manufacturers accompanying documents The product is of Class IIa according to Article 9 of the Directive

Andover, Date

1/Dec/1998

Charles Doucette, (CPD Q&R Mgr.) Authorized EU-representative: Hewlett-Packard GmbH, Medical Production, 71034 Boeblingen (FAX: +4907031-14-2346)

Document No.