



GE Medical Systems
Information Technologies

gemedicalsystems.com

EC Declaration of Conformity

Manufacturer:

GE Medical Systems Information Technologies

8200 West Tower Avenue
Milwaukee Wi 53223 USA

Authorized European Representative:

GE Medical Systems Information Technologies

Munzinger Strasse 3, D-79111
Freiburg, Germany

We herewith declare that the product(s)

Electrocardiograph MAC 1200/1200ST

(including system components and accessories, UMDNS Code 16-231)

fulfills the requirements of the following directives, standards and normative documents:

1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
2. EN 60601-1:1990, A1:1993, A2:1995; Medical Electrical Equipment - Part 1: General Requirements for Safety
3. EN60601-1-2:2001; Medical Electrical Equipment- Part 1-2: General Requirements for Safety
Collateral standard: Electromagnetic Compatibility Requirements and Tests
4. EN60601-2-25:1995, A1:1999: Medical Electrical Equipment- Part 2-25: Particular Requirements for the Safety of Electrocardiographs.
5. EN 60601-1-4:1996; Medical Electrical Equipment – Part 1-4: General Requirements for Safety
Collateral Standard: Programmable electrical medical systems

Compliance of a representative sample of the designated product with the "essential requirements" of Annex I of the Directive 93/42/EEC has been certified by

GE Medical Systems Information Technologies

Technical Dossier #

CE-M-090

The medical device has been assigned to class *Ila* as specified in Annex IX of the Directive 93/42/EEC. It bears the mark



The designated product has been designed, manufactured and tested under a quality management system according to EN ISO 9001 and EN ISO 13485 and Annex II Section 3.2 of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:

G-MED France

Date 31-March 2005

Albrecht Malkmus

Senior Regulatory Affairs Engineer

The technical documentation is filed in GE Medical Systems Information Technologies