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 GmbH
Munzinger Strasse 3, D-79111
Freiburg, Germany

We herewith declare that the product(s)

MAC 5500
(including system components and accessories, UMDNS Code 11-411, GMDN 11411)

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. *EN 60601-1-1:2001; Medical Electrical Equipment – Part 1-1: General Requirements for Safety Collateral standard: Safety requirements for medical electrical systems*
4. *EN 60601-1-2:2001; Medical Electrical Equipment – Part 1-2: General Requirements for safety Collateral standard: Electromagnetic compatibility Requirements and Tests*
5. *EN 60601-2-25:1995,A1:1999; Medical Electrical Equipment – Part 2-25: Particular Requirements for the Safety of Electrocardiographs.*
6. *EN 60601-1-4:1996; A1:1999; 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
CE Certificate N° 0704 / B2P3 / 4
ISO Certificate N° 0080 / 9002 – 46002 – 13488 / 4, 0704 / 9001 – 46001 / 1

Technical Dossier #
CE-M-049

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

CE
0459

The designated product has been designed, manufactured and tested under a quality management system according to EN ISO 9001 and 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

Lisa M Baumhardt Date August 17, 2005

Lisa M. Baumhardt
Regulatory Affairs Specialist

The technical documentation is filed in:
GE Medical Systems *Information Technologies*
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Milwaukee, WI 53223 USA