GE Healthcare
Technologies

EC Declaration of Conformity

EG Konformitätserklärung

Document No. DOC0327154

Manufacturer/ Hersteller:
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Authorized EU Representative/ EU Repräsentant:
GE Medical Systems Information Technologies GmbH
Munzinger Strasse 3, D-79111
Freiburg, Germany

We herewith declare that the product/ *Wir erklären hiermit, dass das Produkt*

MAC 400 *Version 1.02*
(including system components and accessorie/*einschließlich Systemkomponenten und Zubehör)*
UMDNS-Code: 11411*; GMDN-Code:11-411*

fulfills the requirements of the following directives, standards and normative documents:
mit den folgenden Richtlinien, Normen und normativen Dokumenten übereinstimmt:

1. *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*
2. *EN 60601-1:1990, A1:1993, A2:1995; A13:1996; Medical Electrical Equipment - Part 1: General Requirements for Safety*
3. *EN 60601-1-2:2001; Medical Electrical Equipment – Part 1-2: General Requirements for safety Collateral standard: Electromagnetic compatibility Requirements and Tests*
4. *EN 60601-2-25:1995,A1:1999; Medical Electrical Equipment – Part 2-25: Particular Requirements for the Safety of Electrocardiographs.*
5. *EN 60601-1-4:1996; A1:1999; Medical Electrical Equipment – Part 1-4: General Requirements for Safety Collateral Standard: Programmable electrical medical systems*
6. *EN 60601-2-51: 2003 Particular requirements for safety, including essential performance, of recording and analysis single channel and multichannel electrocardiographs*

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:
Die Übereinstimmung eines Baumusters des bezeichneten Produktes mit den "grundlegenden Anforderungen" gemäss Anhang I der Richtlinie 93/42/EWG wird bescheinigt durch:

GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA
Technical Dossier CE-A-002

The medical device has been assigned to class <**IIa** > as specified in Annex IX of the Directive 93/42/EEC. It bears the mark
Das Medizinprodukt ist eingestuft in die Klasse <**IIa** > *gemäss Anhang IX der Richtlinie 93/42/EWG, es trägt die Kennzeichnung*

CE
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The designated product has been designed, manufactured and tested under a quality management system according to **<EN ISO 9001: 2000>**, EN ISO 13485: 2003 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:

Das bezeichnete Produkt wurde unter Anwendung des Qualitätsmanagementsystems gemäss **<EN ISO 9001:2000>**, *ISO 13485:2003 und Anhang II, Abschnitt 3.2 der Richtlinie 93/42/EWG über Medizinprodukte entwickelt, hergestellt und geprüft. Die Konformität des Qualitätsmanagementsystems wird bescheinigt durch:*

G-MED France

Matthias Buerger 30 October 2007

Matthias Buerger *Date*
Director, Global QA/RA
Wauwatosa, Wisconsin

The technical documentation is filed at Research Park, Wauwatosa, WI
Die technische Doukmentation ist archiviert in Research Park, Wauwatosa, WI