

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 accessories/*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

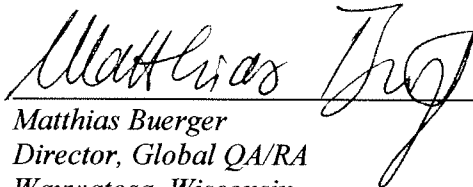
Das Medizinprodukt ist eingestuft in die Klasse <IIa> gemäss Anhang IX der Richtlinie 93/42/EWG, es trägt die Kennzeichnung



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

 30 October 2007
Matthias Buerger Date
Director, Global QA/RA
Wauwatosa, Wisconsin

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

