



EC Declaration of Conformity

EG Konformitätserklärung

Document No. **DOC0711295**

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**

Munzingerstrasse 5
79111 Freiburg, Germany

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

MAC 600

(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; Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance*
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, A1:2006 (IEC 60601-1-2:2004); Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - 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 (IEC 60601-1-4:2000); Medical Electrical Equipment – Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems*
7. *EN 60601-2-51: 2003; Medical Electrical Equipment – Part 2-51; Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs*
8. *EN 60601-1-6; 2007; Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard Usability*

Compliance of the designated product with the Directive 93/42/EEC has been certified by:

Die Übereinstimmung des bezeichneten Produktes mit 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-005

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

GE Healthcare

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

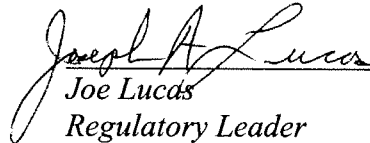


The designated product has been designed and manufactured under a quality management system according to EN ISO 13485: 2003 and Annex II of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:

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

G-MED France

 Jan 15, 2010
Date
Dave Wahlig
Director, Regulatory Affairs
Wauwatosa, Wisconsin

 Jan. 15, 2010
Date
Joe Lucas
Regulatory Leader
Wauwatosa, Wisconsin

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