GE Healthcare

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 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; 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 Requirments 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

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

CE
0459

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
Dave Wahlig *Date*
Director, Regulatory Affairs
Wauwatosa, Wisconsin

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

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