Technologies

EC Declaration of Conformity

EG Konformitätserklärung

Document No. DOC0332638

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 1600 *Version 1.0*
MAC16-XXXXXX-XXXXXX
(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. *IEC 60601-1-1: 2000; Medical Electrical Equipment – Part 1-1: General Requirements for Safety Collateral standard: Safety requirements for medical electrical systems*
4. *IEC 60601-1-2:2007; 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. *IEC 60601-1-4:2000; Medical Electrical Equipment – Part 1-4: General Requirements for Safety Collateral Standard: Programmable electrical medical systems*
7. *IEC 60601-2-51: 2003 Particular requirements for safety, including essential performance, of recording and analysis single channel and multichannel electrocardiographs*
8. *IEC 60601-1-6: 2006 Medical electrical equipment - Part 1-6: General Requirements for Safety - Collateral standard: Usability*

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-M-138

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*

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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

11 July 2008

Matthias Buerger
Director, Global QA/RA
Wauwatosa, Wisconsin

Date

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