GE Medical Systems Information Technologies

EC Declaration of Conformity

EG Konformitätserklärung

Document No. DOC0519258

Manufacturer/ Hersteller:
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, Wisconsin 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 800 Version 1.0
MAC8-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. *IEC 60601-1:1990, Medical Electrical Equipment Part 1: 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*
3. *IEC 60601-1-2:2001/A1:2004, Medical electrical equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Capability*
4. *IEC 60601-1-4:2000 (IEC 60601-1-4:1996, +A1:1999), Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems*
5. *EN60601-2-25:1995; Medical Electrical Equipment-Part 2-25: Particular requirements for the safety of electrocardiographs*
6. *IEC 60601-2-51:2003; Medical Electrical Equipment-Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs*
7. *IEC 60601-1-4:2006; 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:

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Technical Dossier #CE-M-150

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*

GE Medical Systems Information Technologies

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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

Stefanie Koenig
Director, QA/RA
Wauwatosa, Wisconsin USA

21 JAN 2009
Date

The technical documentation is filed at GE Medical Systems Information Technologies- *RP*
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Die technische Doukmentation ist archiviert bei GE Medical Systems Information Technologies-*RP*
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