



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 15 07 44649 031

**Manufacturer:** Philips Medical Systems

3000 Minuteman Road  
Andover MA 01810-1099  
USA

**EC-Representative:** Philips Medizin Systeme  
Böblingen GmbH

Hewlett-Packard Strasse 2  
71034 Böblingen  
GERMANY

**Product  
Category(ies):**

Single and Multi-Parameter Patient Monitors  
(Transport, Point-of-Care, Central Unit, Home Use);  
Defibrillators and Related Accessories (Including  
Cables, Electrodes, Recorders and Paddles) for  
ECG, CPR Feedback, Pulse Oximetry, Respiration  
and Gas Monitoring, Blood Pressure (Invasive and  
Non-Invasive), Temperature and Clinical Information  
Systems; Cardiographs and Related Accessories  
(Including Electrodes, Cables, Lead Sets and Paper),  
ECG Systems; ICG Systems; Telemetry Systems and  
Related Accessories (Including Cables and Lead Sets);  
Clinical Information Systems; Fetal ECG Electrodes;  
Temperature Probes; Transesophageal Sheath Kits,  
Oesophageal Monitoring Feeding Tubes; Picture  
Archiving and Communicating System, Cutaneous  
Bilirubin Analyzers, Phototherapy Devices and  
Thermoregulation Devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 72104383  
**Valid from:** 2015-08-25  
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Hans-Heiner Junker

**Date,** 2015-08-20



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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(Devices in Class IIa, IIb or III)****No. G1 15 07 44649 031****Facility(ies):****Philips Medical Systems  
3000 Minuteman Road, Andover MA 01810-1099, USA****Philips Medical Systems Inc.  
STE 175W 951 Yamato Road, Boca Raton FL 33431, USA**