Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08

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 044649 0046 Rev. 00

Manufacturer:

Philips Medical Systems
3000 Minuteman Road
Andover MA 01810-1099
USA

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), EEG and Temperature; 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.: 72150337

Digitally signed by Ermicev Alexandr
Date: 2021.05.19 14:44:45 EEST
Reason: MoldSign Signature
Location: Moldova

Valid from: 2020-04-07
Valid until: 2024-05-26

Date, 2020-04-07

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany