Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 011882 0079 Rev. 00

Manufacturer:

PHYSIO-CONTROL, Inc.
11811 Willows Road N.E.
Redmond WA 98052
USA

Product Category(ies):

ECG Monitors, Manual and Automatic External Defibrillators, External Transcutaneous Pacemakers, with the Following Optional Patient Parameter Monitoring Capability: Pulse Oximetry, Invasive and Non-Invasive Blood Pressure, Capnography (ETC02), Temperature, and Patient Data Management System.

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.: 72151769

Valid from: 2020-03-18
Valid until: 2024-05-26

Date, 2020-03-18

Christoph Dicks
Head of Certification/Notified Body

Signature Not Verified
Dokument podpisany przez Małgorzata Adamczyk
Data: 2023.09.11 10:50:19 CEST

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

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