EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1624046-1

Manufacturer: GETEMED Medizin- und Informationstechnik AG
Oderstr. 77
14513 Teltow
Germany

Products: Vital signs monitors, cardiac function diagnostic and telemonitoring Systems

Product groups included:

Recorder, Long-term ECG portable:
- CardioMem® and SEER

Long-term ECG evaluation system:
- CardioDay®

Electrocardiograph, multi-channel:
- CardioLink®

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3339850-30

Effective date: 2021-04-16

Expiry date: 2024-05-26

Issue date: 2021-04-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1624046-1

Manufacturer: GETEMED Medizin- und Informationstechnik AG
Oderstr. 77
14513 Teltow
Germany

Product groups included:

Pulse oximeter, physiological monitoring system, neonatal:
- VitaGuard® with VitaWin®

ECG-monitor, telemetric:
- PhysioMem®

Computer, ECG evaluation:
- HeartX®

Transmission / receiving system, telephone, physiologic monitor:
- PhysioGate®

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