ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD 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 041505 0120 Rev. 00

Manufacturer:

SCHILLER AG
Altgasse 68
6341 Baar
SWITZERLAND

Facility(ies):

SCHILLER Engineering Austria GmbH
Defreggergasse 5, 8020 Graz, AUSTRIA

SCHILLER AG
Altgasse 68, 6341 Baar, SWITZERLAND

Product Category(ies):

Electrocardiographs, ECG Holters, ECG Analysis Software, Spirometers, Sphygmomanometers, Monitoring Devices, Monitoring Systems, Central Monitoring Systems, Cardiopulmonary Exercise Testing Systems, Defibrillators, Telemetry Devices and Cardiopulmonary Resuscitation 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.: 713154696

Valid from: 2019-04-17
Valid until: 2024-04-16

Date, 2019-04-17

Stefan Preiß

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

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

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