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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 041505 0132 Rev. 02

Manufacturer:

SCHILLER AG
Altgasse 68
6341 Baar
SWITZERLAND

SRN Manufacturer - CH-MF-000012722

Authorized Representative:

Schiller Medizintechnik GmbH
Otto-Lilienthal-Ring 4, 85622 Feldkirchen, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 041505 0132 Rev. 02

Report No.: 713316637

Preceding Certificate No.: G10 041505 0132 Rev. 01

Valid from: 2023-12-15
Valid until: 2026-11-11

Date of Initial Issuance: 2021-11-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-12-15

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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No. G10 041505 0132 Rev. 02

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The ARGUS PB-3000 is a vital data acquisition unit intended to be used within or connected to a medical device or a medical System (Host System) for acquiring, analysing, and transmission of patient vitals and other pertinent clinical data of following vital data of a patient: ECG and Respiration: ECG, heart rate, asystole time, respiration rate and apnoea time for monitoring and diagnostic purpose. IBP: The IBP measurement is intended for continuously invasive measurement of a patient's arterial and/or venous blood pressure in different locations. NIBP: The NIBP measurement is intended for non-invasive measure blood pressure with different cuffs in different locations. SpO2: The SpO2 measurement is intended for non-invasive measuring of a patient's oxygen saturation level and other parameters (e.g. SpCO, SpMet). CO2 and Respiration: The CO2 measurement is intended for the non-invasive monitoring of a patient's in and exhaled carbon dioxide, anaesthesia gases and to provide a respiration rate. Cardiac Output (CO): The Cardiac Output measurement is intended for measuring continuously blood and injected fluid temperature for calculating the current Cardiac Output of a patient in the medical system (Host System). Temperature: The Temperature measurement is intended for non-invasive and invasive measurement of a patient's temperature in different locations.

Classification:	Class IIb
Device Group:	Z120304 - CARDIAC COMPRESSORS
Intended Purpose:	The Easy Pulse is an active therapeutic device intended to do automatic multidirectional chest compression. The device may be used in the following situations: - Primary rescue - Secondary rescue

Classification:	Class IIa
Device Group:	Z120503 - ELECTROCARDIOGRAPHS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12059009 - ECG DATA MANAGEMENT SYSTEMS
Intended Purpose:	-

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No. G10 041505 0132 Rev. 02

Classification:	Class IIa
Device Group:	Z12050392 - ELECTROCARDIOGRAPHS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12050401 - CARDIOVASCULAR HOLTER ANALYSERS
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2021-11-12	713206628	-
01	2023-09-15	713297014	Supplemented: Device(s)/group of device(s) added
02	2023-12-15	713316637	Supplemented: Device(s)/group of device(s) added

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