



## 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. 03**

### 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, Certification, Validation and Verification Regulations 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. 03](http://www.tuvsud.com/ps-cert?q=cert:G10 041505 0132 Rev. 03)

**Report No.:** 713352404

**Preceding Certificate No.:** G10 041505 0132 Rev. 02

**Valid from:** 2024-11-22

**Valid until:** 2026-11-11

**Date of Initial Issuance:** 2021-11-12

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2024-11-22



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**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:**

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**Classification:**

Class IIa

**Device Group:**

Z12059009 - ECG DATA MANAGEMENT SYSTEMS

**Intended Purpose:**

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

**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z120504 - HOLTER SYSTEM INSTRUMENTS FOR CARDIOVASCULAR PARAMETERS

**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
03	2024-11-22	713352404	Amended: Other Supplemented: Change to the approved type(s)/device(s)