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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 052098 0012 Rev. 04

Manufacturer:

Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard Strasse 2
71034 Böblingen
GERMANY

SRN Manufacturer - DE-MF-000006026

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 052098 0012 Rev. 04

Report No.:	713259856
Preceding Certificate No.:	G10 052098 0012 Rev. 03
Valid from:	2024-03-26
Valid until:	2025-10-05
Date of Initial Issuance:	2020-10-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-26

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 052098 0012 Rev. 04

Classification:	Class IIb
Device Group:	Z12030292 - VITAL SIGNS MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	The device is intended for use by healthcare providers whenever there is a need for generation of a patient record. The device is indicated for use in the collection, storage, and management of data from Philips specified measurements and Philips Patient Monitors that are connected through networks

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The device is intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates

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

Classification:	Class IIb
Device Group:	Z120801 - PRENATAL DIAGNOSTIC INSTRUMENTS
Intended Purpose:	The device is intended to be used for monitoring and recording of, and to generate alarms for multiple physiological parameters of pregnant women and the fetus

Classification:	Class IIa
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
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	2020-10-06	713185878	-	
01	2022-05-03	713214514/713214540	-	
02	2023-09-12	713227935	Supplemented: Device(s)/group of device(s) added	
03	2024-01-15	713299424/ 713310771	Supplemented: Other	Add facility
04	2024-03-26	713259856	Supplemented: Device(s)/group of device(s) added	

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