

## **EU Declaration of Conformity**

**PAR Medizintechnik GmbH & Co. KG, Rigistr. 11, 12277 Berlin, Germany**

**Single Registration Number (SRN): DE-MF-000017480**

We declare in our sole responsibility that the medical device(s) listed in the Appendix is (are) in conformity with annexes I, II and III of the Regulation (EU) **2017/745** on medical devices.

The medical device has the following intended purpose:

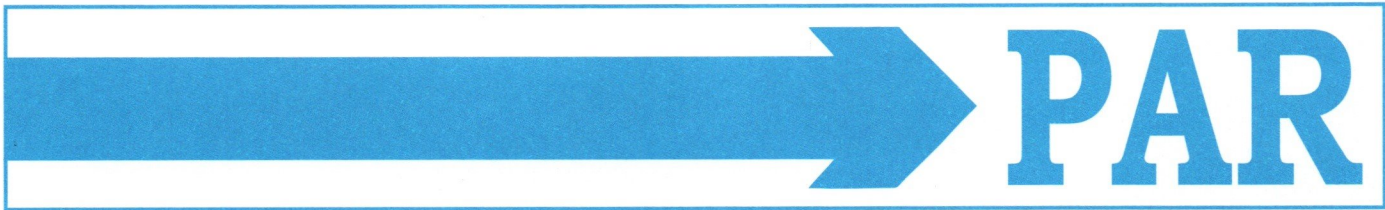
*An ambulatory blood pressure measuring device is intended to be used in combination with a suitable blood pressure cuff for the automatic non-invasive measurement of the blood pressure (single or 24-h-measurement of the systolic, diastolic and mean value), the heart rate and other vital or non-vital sign parameters of human beings in the clinical daily routine.*

The medical device is defined as a class IIa device in accordance with annex VIII rule 10 of the Regulation (EU) **2017/745** on medical devices. It is marked with

**CE 0482**

There are currently no applicable common specifications, for which conformity has to be declared.

The medical device also fulfills the applicable Directive 2011/65/EU (RoHS 2) and the additional delegated Directive (EU) 2015/863 (RoHS 3).



Design and development, manufacture, final inspection, distribution and servicing are carried out using a quality system in accordance with EN ISO 13485:2016 + AC:2018 + A11:2021 and annex IX of the Regulation (EU) 2017/745 on medical devices. The conformity of the quality system is certified by:

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2**  
**20355 Hamburg**  
**Germany**

This document is valid until 2025-02-28.

Number of EC Certificate of Conformity: 2210 GB448220919

Berlin, 2023-02-15

PAR Medizintechnik GmbH & Co. KG

Dipl.-Ing. B. Tek  
General Manager

## Appendix

Device Name	Article Number	Basic-UDI-DI
PHYSIO-PORT	S1851	426067137ABPMonitor3C
PHYSIO-PORT AS	S285	426067137ABPMonitor3C
PHYSIO-PORT DUO	S2440	426067137ABPMonitor3C
PHYSIO-PORT UP	S200	426067137ABPMonitor3C

**GMDN code:** 36888

**UMDNS code:** 12 – 386