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