EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745 and of the directive 2011/65/EU

We:

Manufacturer	EU Authorized Representative
GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226, USA Single Registration Number (SRN): US-MF-000017529	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France SRN: FR-AR-000000344

Manufacturing Site

Manufacturing Facility 1

GE Medical Systems Information Technologies

465 Pan American Drive, Suite 11

El Paso, Texas 79907, USA

Manufacturing Facility 2

GE Healthcare Finland Oy

Kuortaneenkatu 2

00510 Helsinki, Finland

Declare under our sole responsibility that the device:

CardioSoft V7.0 - Cardiac Testing System

SIGNATURE:

Shlomi Deler
Director, Regulatory Affairs
Diagnostic Cardiology (DCAR)
Wauwatosa, Wisconsin, USA

Date: 06-June-2023

Basic UDI-DI: 8406821BUG00157HE

Intended Purpose:

The CardioSoft V7.0 is designed to acquire, process, record, archive, analyze and output (12 and 15 lead suction) data during a period of physiologic stress or during a resting ECG test and acquire data from ancillary devices, such as spirometry and ambulatory blood pressure devices. CardioSoft V7.0 -Cardiac Testing System use is intended for trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients.

EMDN Code	**:**	Z120503- Electrocardiographs
UMDNS Code	**:**	17723 - Physiologic Monitoring Systems, Stress Exercise, Cardiac
GMDN Code	**:**	16231 - Interpretive multichannel electrocardiograph

Class: IIa

Classification rule (Annex VIII): Rule 10

SIGNATURE:

Shlomi Deler
Director, Regulatory Affairs
Diagnostic Cardiology (DCAR)
Wauwatosa, Wisconsin, USA

Date: 06-June-2023

This EC declaration of conformity supersedes the previous declaration dated 14 October 2021

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it

This conformity is based on the following elements:

- Technical Documentation reference DOC2539878, of the product to which this declaration relates.
- ISO13485:2016: Approval of Quality Management System delivered by TUV Rheinland, Germany/ Certificate SX 60146867 0001
- EC certificate N : HZ 2214580-1
    - Conformity assessment procedure followed: Annex IX, Chapters I, III
    - Delivered by TUV Rheinland (0197)
- List of applicable Standards: Refer to General Safety and Performance Requirement (DOC2512720)

SIGNATURE:

Shlomi Deler
Director, Regulatory Affairs
Diagnostic Cardiology (DCAR)
Wauwatosa, Wisconsin, USA

Date: 06-June-2023

This is the initial EC declaration of conformity to be released under medical devices regulation 2017/745

End of Document

EU Declaration of Conformity

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

SRN: DE-MF-000017480

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

Intended Purpose: The cuff is a medical device used in combination with portable ambulatory blood pressure measurement devices or blood pressure measurement modules for the non-invasive measurement of the blood pressure. The cuff acts as a transducer for the pressure oscillations from which the blood pressure (systolic and diastolic value) is determined. It is connected to a blood pressure measurement device by a tube. The cuff is wrapped around the uninjured naked arm of the patient and then inflated with air. The cuff is selected for children and adults according to the marked circumference of the upper arm.
The cuff is not sterilised. There are reusable as well as single-use cuffs available, which have different cuff fabric and connector from each other.
The reusable cuffs can be cleaned with a wet cloth and disinfected. Liquid shall not ingress into the tube or the bladder of the cuff.
The single-use cuff is connected to a blood pressure measurement device or a module by inserting an adapter between the device and the tube of the single-use cuff. It shall not be reused. One single application on a patient is the use for a 24 h blood pressure measurement in combination with a blood pressure device. The cuff is applied on the patient by medical staff only in the physician's practice or in a hospital. The usage of cuff is instructed to patients. The cuff is not suitable for neonates. The application of the cuff is prohibited on an arm with dialysis shunt, fresh operation wounds, or mastectomy. Damaged cuff can lead to erroneous measurements.
If the doctor ascertains a positive benefit-risk-ratio, the application of the cuff is allowed on the arm with lymphedema, paresis or plegia, arterial or venous vascular access.

The medical device is defined as a class I device in accordance to annex VIII rule 1 of the MDR.
It is marked with

CE

The medical device is designed, developed, manufactured, final inspected, distributed and serviced under control of a quality system in accordance to EN ISO 13485:2016 + AC:2016. The conformity of the quality system is certificated by:

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

Berlin, March 01, 2023

PAR Medizintechnik GmbH & Co. KG

Dipl.-Ing. B. Tek
General Manager

Appendix

Device Name	Article Number	GE-PN#	GMDN-Code
TONOPORT BP Cuff for Adults, Small	A4215-s	2001589-211	34978
TONOPORT BP Cuff for Adults, Standard	A4215-m	2001589-212	
TONOPORT BP Cuff for Adults, Large	A4215-l	2001589-213	
TONOPORT BP Cuff for Adults, Extra-Large	A4215-xl	2001589-214	
TONOPORT BP Single-Use Cuff for Adults, Small	A4216-s	2001589-232	37326
TONOPORT BP Single-Use Cuff for Adults, Standard	4216-m	2001589-233	
TONOPORT BP Single-Use Cuff for Adults, Large	4216-l	2001589-234	
TONOPORT BP Single-Use Cuff for Adults, Extra-Large	4216-xl	2001589-235	

UMDNS code: 11 – 073 **Basic-UDI-DI:** 426067137NIBPCuff6F

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 2024-12-31.

Number of EU Quality Management System Certificate: 2210GB448220919

Berlin, 2022-11-15

PAR Medizintechnik GmbH & Co. KG

Dipl.-Ing. B. Tek
General Manager

Appendix

Device Name	Version	Article Number	Basic-UDI-DI
TONOPORT VI	HW 1.0, FW 3.0	S350	426067137ABPMonitor3C

GMDN code: 36888 **UMDNS code:** 12 – 386