EU Declaration of Conformity

PAR Medizintechnik GmbH & Co. KG, Sachsendamm 6, 10829 Berlin

We declare in our own responsibility that the medical device

TONOPORT VI, Hardware-Version **HW 1.0,** Firmware-Version **FW 3.0**
(UMDNS-code: 12 – 386)

is in conformity with
annex 1 (essential requirements) of the Medical Device Directive **93/42/EEC**
including amendment **2007/47/EC**

The medical device is defined as class IIa device in accordance to annex IX rule 10 of the Medical Device Directive. It is marked with

CE - 0482

The medical device is designed, produced and verified under control of a quality system in accordance to EN ISO 13485:2012 + AC:2012 and annex II of the Medical Device Directive. The conformity of the quality system is certificated by:

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

This document is valid until June 30, 2020.

Berlin, February 19, 2018

PAR Medizintechnik GmbH & Co. KG

Engel

Dipl.-Ing. L. Engel
R&D and Quality Manager

Accessories for TONOPORT VI:

Item Number	Item Description
2001589-211	TONOPORT BP CUFF ADULT SMALL
2001589-212	TONOPORT BP CUFF ADULT STANDARD
2001589-213	TONOPORT BP CUFF ADULT LARGE
2001589-214	TONOPORT BP CUFF ADULT EXTRA LARGE
2001589-215	BP WEARABLE POUCH TONOPORT VI
2001589-016	SPLY BP BAG BELT TONOPORT V
2001589-041	BTRY CHGR NIMH /2
2001589-014	BTRY RECHGR NIMH SIZE AA
2001589-040	CABLE TONOPORT V - PC (USB)
2001589-011	CABLE TONOPORT V - PC
2001589-093	CD USB DRIVER TONOPORT V /2.1
2001589-216	CARRYING CASE TONOPORT VI SYSTEM
2001589-201	SYSTEM TONOPORT VI VAN
2001589-202	TONOPORT VI