Declaration of Conformity

Manufacturer: WR Medical Electronics Co.	**Address:** 1700 Gervais Ave. Maplewood, MN 55109 USA
Product Group: Heart Rate Variability - Neurological	
Product Family: HRV	
Device Name: HRV Acquire	
Product Part Number(s): 5650	
Device Classification Per MDD: Class IIa, per Rule 10	
Year of Manufacture: 2021	
RoHS2 Declaration: The HRV Acquire conforms to the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, Restriction of Hazardous Materials (RoHS). Conformance is based on declarations received from our suppliers that the products and raw materials they supply comply with 2011/65/EU and do not contain substances as outlined in Annex II of the directive.	
RoHS2 Declaration Based On: Directive 2011/65/EC	
European Representative: Medical Device Safety Service GmbH, Schiffgraben 41, 30175, Hannover, Germany	
Notified Body: Intertek SEMKO AB (0413)	
Declaration: WR Medical Electronics Co. hereby declares that the medical device specified above, to which this declaration relates, is in conformance with the essential requirements of Council Directive 93/42/EEC Medical Device Directive under Annex II (EC Declaration of Conformity; Production Quality Assurance), and with Swedish National Legislation under LVFS 2003:11.	
Declaration Based On: Device Directive 93/42/EEC for Medical Devices	
Certificate No.: 41314493-02	**Issued by**: Intertek SEMKO AB
Prepared By: Quality Steering Team	
Devices not manufactured by WR Medical Electronics Co.: WR Medical Electronics Co. approves the HRV Acquire for use with the CNAP Blood Pressure Monitor 500 manufactured by CNSystems.	
Declaration of Conformance Issued By: Mr. Kyle Maloney, President and CEO, WR Medical Electronics Co. 1700 Gervais Ave, Maplewood, MN 55109 USA	
(Mr. Kyle Maloney)	3/5/2021 (Date)
Rev 6	