Declaration of Conformity

Manufacturer: WR Medical Electronics Co.	**Address:** 1700 Gervais Ave Maplewood, MN 55109 USA
Product Group: Quantitative Sweat Testing Device – Neurological	
Product Family: Autonomic and Sensory Testing Systems	
Device Name: Q-Sweat™	
Product Part Number(s): 5188	
Device Classification Per MDD: Class I – Measuring, per Rule 1	
Year of Manufacture: 2021	
RoHS2 Declaration: The Q-Sweat™ 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; Full Quality Assurance System), and with Swedish National Legislation under LVFS 2003:11.	
Declaration Based On: Annex II of the Device Directive 93/42/EEC for Medical Devices	
Certificate No.: 41314493	**Issued by:** Intertek Semko AB
Declaration of Conformance Issued By: Mr. Kyle Maloney, President & CEO; WR Medical Electronics Co. 1700 Gervais Ave, Maplewood, MN, 55109, USA	
Prepared By: Quality Steering Team	
(Mr. Kyle Maloney) 3/5/2021 (Date)	
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