Declaration of Conformity

Manufacturer: WR Medical Electronics Co.	**Address:** 1700 Gervais Ave Maplewood, MN 55109 USA
Product Group: Baths, Paraffin, Physical Therapy	
Product Family: Therabath® Professional Grade Paraffin Bath	
Device Name: Therabath® TB6, TB7, TB9 and TB10	
Product Part Number(s): 2275 through 2400	
Device Classification Per MDD: Class IIa - per Rule 9	
Year of Manufacture: 2019	
RoHS2 Declaration: The Therabaths, TB6, TB7, TB9 and TB10, conform 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. MDSS is the designated Authorized Representative only for the MDD 93/42/EEC.	
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: Device Directive 93/42/EEC for Medical Devices	
Certificate No.: 41314493	**Issued by:** Intertek SEMKO AB
Declaration of Conformance Issued By: Ms. Amanda Johnsen, Operations Manager; WR Medical Electronics Co. 1700 Gervais Ave, Maplewood, MN, 55109, USA	
Prepared By: Quality Steering Team	
(Ms. Amanda Johnsen)	12-04-19 (Date)
Rev 2.3	