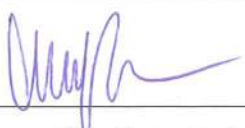


## Declaration of Conformity

<b>Manufacturer:</b> WR Medical Electronics Co.	<b>Address:</b> 1700 Gervais Ave Maplewood, MN 55109 USA
<b>Product Group:</b> Baths, Paraffin, Physical Therapy	
<b>Product Family:</b> Therabath® Professional Grade Paraffin Bath	
<b>Device Name:</b> Therabath® TB7 and TB10	
<b>Product Part Number(s):</b> For TB7 – 2298, 2302, 2312, 2322, 2332, 2356, 2358, 2373, 2379, 2382, 2390, 2395. For TB10 – 2280, 2281.	
<b>Device Classification Per MDD:</b> Class IIa - per Rule 9	
<b>RoHS2 Declaration:</b> The Therabaths, TB7 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.	
<b>RoHS2 Declaration Based On:</b> Directive 2011/65/EC	
<b>European Representative:</b> Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany. MDSS is the designated Authorized Representative only for the MDD 93/42/EEC.	
<b>Notified Body:</b> Intertek Semko AB (0413)	
<b>Declaration:</b> 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.	
<b>Declaration Based On:</b> Device Directive 93/42/EEC for Medical Devices	
<b>Certificate No.:</b> 41314493-02	<b>Issued by:</b> Intertek SEMKO AB
<b>Declaration of Conformance Issued By:</b> Ms. Amanda Johnsen, Director of Operations; WR Medical Electronics Co. 1700 Gervais Ave, Maplewood, MN, 55109, USA	
<b>Prepared By:</b> Quality Steering Team	
 _____ (Ms. Amanda Johnsen)	05-13-21 _____ (Date)
Rev 3	