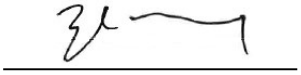
Declaration of Conformity

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: Refill Paraffin Wax for the Therabath® TB7 and TB10	
Product Part Number(s): 0100, 0101, 0102, 0103, 0104, 0105, 0106, 0107, 0108, 0122, 0129 0130, 0150, 0151, 0153, 0154, 0159.	
Device Classification Per MDD: Class I - per Rule 1	
RoHS 3 Declaration: The Therabaths, TB7 and TB10, conform to the Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards to the list of restricted substances; Restriction of Hazardous Materials (RoHS). Conformance is based on declarations received from our suppliers that the products and raw materials they supply comply with 2015/863/EU and do not contain substances as outlined in Annex II of the directive.	
RoHS 3 Declaration Based On: Directive 2015/863/EU	
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 excluding (4) (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.: 41314493-02	**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)	January 31, 2025 (Date)
Rev 4	