

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® TB7

Product Part Number(s): 2300, 2302, 2310, 2312, 2320, 2322, 2330, 2332, 2340, 2342, 2350, 2352, 2370, 2372, 2373, 2375, 2378, 2379, 2382, 2383, 2386, 2389

Device Classification Per MDD: Class IIa - per Rule 9

Year of Manufacture: 2011

European Representative: Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany

Annex V Notified Body: SEMKO (Sweden) (0413)

Technical File No: RA-1, Revision D, 24 September 2010

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 2001:6.

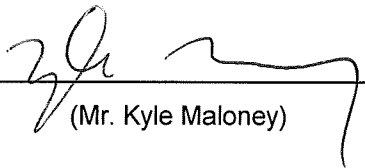
Declaration Based On: Annex II of the Directive 93/42/EEC on Medical Devices

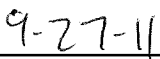
Certificate No.: 41314523

Issued by: Intertek SEMKO AB

Declaration of Conformance Issued By: Mr. Kyle Maloney, Engineering Manager, WR Medical Electronics Co. 1700 Gervais Ave, Maplewood, MN 55109 USA

Prepared By: Quality Steering Team


(Mr. Kyle Maloney)


(Date)