

Declaration of Conformity

Manufacturer:
WR Medical Electronics Co.

Address:
123 North Second Street
Stillwater, MN 55082-5047
USA

Product Group: Baths, Paraffin, Physical Therapy

Product Family: Therabath® Pro® Professional Grade Paraffin Bath

Device Name: Accessories for the Therabath® Pro® TB4, TB5

Product Part Number(s): 0100, 0101, 0102, 0107, 0122, 0124, 2400, 2401, 2402, 2410, 2411, 2420, 2421, 2412, 2209, 0205, 0206, 0210, 0208, 0209, 2430, 2431,

Device Classification Per MDD: Class I - per Rule 1

Year of Manufacture: 2004

European Representative: Medical Device Safety Service GmbH, Burckhardtstr 1, D-30163, Hannover, Germany

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

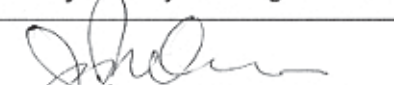
Technical File No: RA-1, Revision B, 9 February 2004

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 VII, and with Swedish National Legislation under LVFS 2001:6.

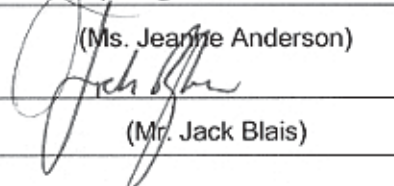
Declaration Based On: Annex VII of the Directive 93/42/EEC on Medical Devices

Declaration of Conformance Issued By: Ms. Jeanne Anderson, Director of Regulatory and Clinical Affairs, Mr. Jack Blais, Executive Vice President, WR Medical Electronics Co. 123 North Second Street, Stillwater, MN 55082-5047 USA

Prepared By: Quality Steering Team and Director of Regulatory and Clinical Affairs



(Ms. Jeanne Anderson)



(Mr. Jack Blais)

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(Date)

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(Date)