

Declaration of Conformity

Manufacturer: **WR Medical Electronics Co.**

Address:

**123 North Second Street
Stillwater, MN 55082-5047
USA**

Product Group: **Quantitative Sweat Testing Device - Neurological**

Product Family: **Q-Sweat™**

Device Name: **Q-Sweat™**

Product Part Number(s): **5188**

Device Classification Per MDD: **Class I-Measuring, per Rule 1**

Year of Manufacture: **2003**

European Representative: **Medical Device Safety Service GmbH, Burckhardtstrasse 1, D-30163 Hanover, Germany**

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

Technical File No: **RA-3, Revision A, 23 June 2003**

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 V (EC Declaration of Conformity; Production Quality Assurance), and with Swedish National Legislation under LVFS 2001:6.**

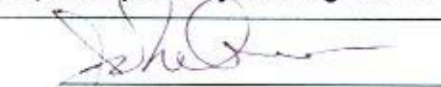
Declaration Based On: **Annex V of the Directive 93/42/EEC on Medical Devices**

Certificate No.: **41314373**

Issued by: **Intertek Semko AB**

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**

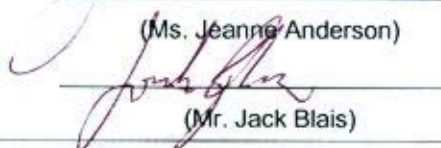
Prepared By: **Quality Steering Team and Director of Regulatory and Clinical Affairs**



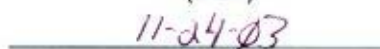
(Ms. Jeanne Anderson)



(Date)



(Mr. Jack Blais)



(Date)