

MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian *Therapeutic Goods (Medical Devices) Regulations 2002* relating to the stated devices.

Manufacturer's Name: WR Medical Electronics Co.

Business Address: 123 N. Second St., Stillwater, MN 55082

Medical Devices: CASE IV Computer Aided Sensory Evaluator

Classification: II a

GMDN Code and Term: Quantitative Sensory Tester, Thermal Analysing System
[37350]

Scope of Application: All

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate:

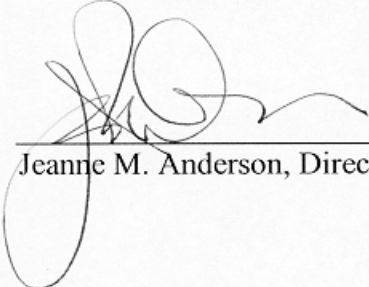
Equivalent Overseas Certification: European Medical Devices Directive Annex II without Clause 4 Certificates:
Intertek Testing Services Ltd. NA, *Certificate No. US-2296* (ISO 9001:2000) and
Certificate No. 9107 (ISO 13485: 1996).

Design Examination Certificate:

Equivalent Overseas Certification: European Medical Devices Directive Annex II
Clause 4 Certificate: EMC Verification No. 3021355.012 – 172,;

Standards Applied: European Harmonised Standards: Emissions: EN 60601-1-2:1993,
Section 36.201 / EN 55011:1991, Class A; Immunity: EMC Directive 89/336/EEC.

Authorised Signatory:



Jeanne M. Anderson, Director of Regulatory Affairs

8/5/04

Date