

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 169219 Symbiotic Devices Pty Ltd - Quantitative sensory tester, thermal analysing system

ARTG entry for Medical Device Included Class Im

Sponsor Symbiotic Devices Pty Ltd

Postal Address Suite 138 / 245 Thomas Street, DANDENONG, VIC, 3175

Australia

ARTG Start Date 18/02/2010

Product Category Medical Device Class Im

Status Active

Approval Area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name Address

WR Medical Electronics Co 1700 Gervais Avenue MaplewoodMN 55109

, ,

United States Of America

Products

1. Quantitative sensory tester, thermal analysing system

Product Type Medical device system Effective Date 18/02/2010

GMDN 37350 Quantitative sensory tester, thermal analysing system

Intended Purpose The Q-Sweat? Quantitative Sweat Measurement System is designed to measure the sweat output of human skin. This device does

not make a diagnosis or indicate that any disease state exists.

CONTRAINDICATIONS:

? Do not conduct this test on fragile or broken skin.

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.