



Certificate Number: AU Q00110/03

CONFORMITY ASSESSMENT CERTIFICATE
FULL QUALITY ASSURANCE PROCEDURES

Schedule 3 – Part 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Australia)

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3 – Part 1, excluding clause 1.6, of the Therapeutic Goods (Medical Devices) Regulations 2002. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

TGA File Number: 2010/003296

Manufacturer Name: Care Essentials Pty Ltd

Address: 25-27 Slevin Street
North Geelong VIC 3215
Australia

Facility: As above

Scope of the certification: Heating unit, pad, air, control unit [GMDN 36954]

Automatic Conditions: apply under section 41EJ of the *Therapeutic Goods Act 1989*

Additional Conditions: NIL

Commencement Date: 05 Oct 2007

Re-issue date: 23 Nov 2010

Expiry date: 05 Oct 2012

This certificate is valid from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.

Rodolfo Ferrari
Delegate of the Secretary
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Therapeutic Goods Administration
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