



Certificate Number
MRA Q00078

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

EC Certificate

Full Quality Assurance System

Annex II excluding (4) of Directive 93/42/EEC on Medical Devices

This is to certify that the Full Quality Assurance System described below conforms to the relevant provisions of Annex II (excluding section 4) of the Council Directive 93/42/EEC on medical devices. Certification is based on an assessment of the Full Quality Assurance System which applies at every stage from design to final controls.

Manufacturer Name: Care Essentials Pty Ltd

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

Commencement Date: 26 May 2011

Certificate Expiry Date: 26 May 2016

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

As required under Annex II (5), surveillance assessments will be periodically undertaken by the Notified Body to ensure that the manufacturer continues to apply the approved quality system.

Andrea Kunca
Head, Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
Australia

**Notified Body
Identification Number**

0805



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Scope of Certificate

Manufacturer Facilities

	Name and Address	Scope
1.	25-27 Slevin Street North Geelong VIC 3215 Australia	Warming Machine and Blanket: design, production, release, warehouse and dispatch.

Device Categories

	Description	Limitations (if applicable)
1.	Cocoon Convective Warming System	
2.	Warming Blanket	



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Certificate History

Version	Details	Issue Date	File Reference
1	Initial certification	26 May 2011	2010/015485
Certificate Location (Manufacturer Root File Number):			2010/010622