



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Certificate Number: MRA Q00059/01

CE CERTIFICATE
PRODUCTION QUALITY ASSURANCE SYSTEM
(Annex V of the Directive 93/42/EEC on Medical Devices)

This is to certify that the Production Quality Assurance System described below conforms to the relevant provisions of Annex V of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Quality Management System for production and final inspection to ensure each medical device to which the system is applied conforms to the product described in the Type Examination or the technical documentation as applicable.

TGA File Number: 2008/009806
Manufacturer Name: Uscom Ltd
Address: Level7 10 Loftus Street
SYDNEY NSW 2000
Australia
Facility: As above
Suppliers: n/a
Scope of the certification: Cardiac output unit, ultrasonic [GMDN 17190]
Special Conditions: NIL

Commencement Date: 15 December 2008

Re-issue date:

Expiry date: 15 December 2013

This Certificate is valid for the period indicated subject to periodic and satisfactory surveillance.

CE 0805

Notified to EC. In compliance with Article 17, CE marking shall be accompanied by our identification number: 0805.

Dr Larry Kelly

Head

Office of Devices, Blood and Tissues

Therapeutic Goods Administration

PO Box 100

WODEN ACT 2606 AUSTRALIA

This Certificate is the property of the Therapeutic Goods Administration and must be returned upon demand
C-MRA-5