

Health and
Ageing

Certificate Number: MRA Q00023/01

Date of Issue: 16 December 2003

Period of Validity¹: 16 December 2003 to 16 December 2008**CE CERTIFICATE****PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL****CERTIFICATE**

(Annex V of the Directive 93/42/EEC on Medical Devices)

This is to certify that the Production Quality Assurance System described below conforms with 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 with the product described in the Type Examination or the technical documentation as applicable.

TGA File Number: 2003/038028 & 2003/064645

Manufacturer Name: Uscom Ltd

Address: Level 4, 199 Clarence St.
Sydney NSW 2000
Australia

Facility: As above

Suppliers: Australian Electronic Manufacturing Services Pty Ltd
Unit 47, Slough Business Estate, Slough Ave
Silverwater NSW 2128
Australia

Scope of the certification: GMDNS 34348 – Cardiac output measuring equipment
GMDNS 33315 – Transducer, heart sound

Special Conditions: NIL

Notified to EC under number ²**CE 0805**

Dr Graeme Harris
A/g Director
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606 AUSTRALIA

¹ This Certificate is valid from the date of issue subject to periodic and satisfactory surveillance.

² In compliance with Article 17, CE marking shall be accompanied by our identification number: 0805.

This Certificate is the property of the Therapeutic Goods Administration and must be returned upon demand

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