

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Uscom Ltd

for approval to supply

Uscom Ltd - Cardiac output unit, ultrasonic

ARTG Identifier	137337
ARTG Start date	11/04/2007
Product Category	Medical Device Included Class IIa
GMDN	17190
GMDN Term	Cardiac output unit, ultrasonic
Intended Purpose	Anyone to whom knowledge of cardiac performance is clinically important may benefit from USCOM examination. USCOM allows beat to beat quantitative evaluation of cardiac heamodynamics and can be used to confirm normal cardiac function, detect and quantify abnormal

Manufacturer Details	Address	Certificate number(s)
Uscom Ltd	Level 8 66 Clarence Street Sydney, NSW, 2000 Australia	DV-2018-MC-20830-1

function, and evaluate the effectiveness of cardiovascular therapies.

ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following 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 Act 1989 and Part 5, Division 5.2 (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.

Products Covered by This Entry

1. Cardiac output unit, ultrasonic

Product Specific Conditions

· No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 137337 ARTG Start Date: 11/04/2007