Certificate Number
AU Q00195

Australian Government
Department of Health
Therapeutic Goods Administration

# Conformity Assessment Certificate

## Production Quality Assurance Procedures

### Schedule 3, Part 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

**Issued to**

**Manufacturer Name:** Uscom Limited

**Manufacturer Address:** Level 8 66 Clarence Street
SYDNEY NSW 2000
Australia

**For the Manufacture and Final inspection of the device categories listed on page 2 of this certificate.**

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3, Part 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002.* Certification is based on an assessment of the Production Quality Management System for the production and final inspection to ensure that each medical device to which the system is applied conforms to the type described in the scope of the respective Type Examination certificate (Schedule 3, Part 2) or is in accordance with the technical documentation prepared by the manufacturer under Schedule 3, clause 6.4.

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.

**Commencement Date:** 25 October 2018

**Certificate Expiry Date:** 25 October 2023

This certificate is issued under Section 41EE of the *Therapeutic Goods Act 1989* by:

**Jie ZHOU**
*Signed electronically*
Delegate of the Secretary
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

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# Scope of Certificate

## Manufacturer Facilities

| | Name and Address | Scope |
|---|---|---|
| 1 | Uscom Limited<br>Level 8, 66 Clarence Street<br>SYDNEY NSW 2000<br>Australia | Production, Assembly, Test, Labelling, Final release, Warehousing and dispatch |

## Manufacture and Final Inspection of Device Categories

| | Description | Limitations (if applicable) |
|---|---|---|
| 1 | Non-invasive haemodynamic monitoring system | |
| 2 | Non-portable automatic inflation electronic sphygmomanometer | |

## Critical Suppliers

| | Name and Address | Scope |
|---|---|---|
| 1 | Wavetronics<br>2-6 Skinner Ave<br>RIVERWOOD NSW 2210<br>Australia | Contract manufacturer for Printed Circuit Board Assembly |

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# Certificate History

| Version | Details | Issue Date | File Reference |
|---|---|---|---|
| 1.1 | Initial certification as AU Q00005 | 16 December 2003 | 2003/038028 |
| 1.2 | Change of address from "Level 4 199 Clarence St Sydney NSW 2000 Australia" to "Level 7 10 Loftus Street Sydney NSW 2000 Australia" | 11 June 2004 | 2003/038028 |
| 1.3 | • Deletion of supplier "Australian Electronic Manufacturing Services Pty Ltd"<br>• Change of scope from "GMDNS 34348 – Cardiac output monitor and GMDNS 33315 – Transducer heart sound" to "Cardiac output unit ultrasonic [GMDN 17190]" | 09 October 2007 | 2007/009470 |
| 2.1 | • Recertification<br>• Change certificate number to AU Q00195 | 17 December 2008 | 2008/009806 |
| 3.1 | Recertification | 28 November 2013 | 2013/014502 |
| 3.2 | Addition of new product category: Sphygmomanometer electronic automatic<br>Addition of new critical supplier:<br>Wavetronics<br>2-6 Skinner Ave<br>RIVERWOOD NSW 2210<br>Australia | 20 August 2014 | 2013/024199 |
| 4.1 | Recertification<br>Addition of legal manufacturer as a manufacturing facility with scope<br>Update device category from 'Cardiac output unit, ultrasonic' to 'Non-invasive haemodynamic monitoring system'<br>Update device category from 'Sphygmomanometer, electronic,automatic' to 'Non-portable automatic inflation electronic sphygmomanometer'<br>Change of manufacturer address from 'Level 7, 10 Loftus Street, SYDNEY NSW' to 'Level 8, 66 Clarence Street, SYDNEY NSW' | 23 October 2018 | E18-327018<br>E18-203803 |

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| Version | Details | Issue Date | File Reference |
|---|---|---|---|
| | Updates to certificate version number as TGA internal modification | | |
| 4.2 | Administrative corrections to certificate details | 25 October 2018 | E18-327018<br>E18-203803 |
| Certificate Location (Manufacturer Root File Number): | | | 2010/010776 |

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# Conditions

The following conditions apply automatically under Section 41EJ of the *Therapeutic Goods Act 1989*:

**Entry and inspection powers**

(1) A conformity assessment certificate is subject to the conditions that the manufacturer in respect of whom the certificate is issued will:
  (a) allow an authorised person:
    (i) to enter, at any reasonable time, premises (including premises outside Australia) at which the person or any other person deals with medical devices of a kind covered by the certificate; and
    (ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and
    (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
  (b) if requested to do so by an authorised person:
    (i) produce to the person such documents relating to devices of a kind covered by the certificate, or to the manufacturer's quality management system, as the person requires; and
    (ii) allow the person to copy the documents.

**Review**

(2) A conformity assessment certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will cooperate in any review by the Secretary of the certificate to determine whether the conformity assessment procedures relating to the following matters have been applied to the kinds of medical devices covered by the certificate:
  (a) the application of quality management systems for the manufacture of medical devices;
  (b) the certification of compliance with the essential principles;
  (c) any other requirement of the conformity assessment procedures specified in the regulations made for the purposes of subsection 41EC(2).

**Notification of substantial changes**

(3) A conformity assessment certificate is subject to the condition that the person in respect of whom the certificate is issued will notify the Secretary, in writing, of any plan for substantial changes to:
  (a) quality management systems; or
  (b) the product range covered by those systems; or
  (c) the product design of kinds of medical devices;
  in respect of which the certificate is issued.

**Fees**

(4) A conformity assessment certificate is subject to the condition that the applicant for the certificate will pay a fee, prescribed in the regulations, for a review under subsection (2), when the fee becomes due and payable.

(5) The regulations may prescribe different levels of fees for different kinds of manufacturers and medical devices.

**Conditions in regulations**

(5A) A conformity assessment certificate is subject to any conditions prescribed by the regulations for the purposes of this subsection.

**Conditions do not limit other conditions**

(6) A condition imposed under this section is in addition to any conditions imposed under this Division.