



Therapeutic  
Goods  
Administration

PO Box 100, Woden, ACT 2606, Australia  
Telephone: (06)232 8444. Fax: (06)232 8581

TGAIN: 104448

## CERTIFICATE OF LISTING

**Listing Name of Therapeutic Goods:**

ATCOR MEDICAL PTY LTD BLOOD PRESSURE MEASURING DEVICES NON-STERILE {ATCOR MEDICAL WEST RYDE NSW, AUST}

**ARTG Listing Number:**

AUST L 64615

**Commencement Date of Listing**

10 June 1998

**Sponsor:**

ATCOR MEDICAL PTY LTD

**Sponsor Enterprise ID:** 20833

**The above Therapeutic goods are listed in the Australian Register of Therapeutic goods subject to the following conditions: -**

1. *Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*
2. *Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*

**CERTIFIED ORIGINAL**

Contact Officer: Ian Hart

TGAIN: 148477-9  
ENT ID: 20833

Atcor Medical Pty Ltd  
Unit 11 1059-1063 Victoria Rd  
WEST RYDE NSW 2114

ATTENTION: A.R Harricks

**NOTIFICATION OF APPROVAL OF AN ADDITION OF A PRODUCT TO A  
LISTING OF THERAPEUTIC DEVICES**

- Products:**
- 1. SPHYMOCOR PX PULSE WAVE ANALYSIS MODEL  
SCOR-PX**
  - 2. SPHYMOCOR VX PULSE WAVE VELOCITY  
SYSTEM MODEL SCOR-VX**
  - 3. SPHYMOCOR MX PULSE WAVE MONITORING  
SYSTEM MODEL SCOR-MX**

**Manufacturer:** ATCOR MEDICAL PTY LTD – ENT ID: 20833

Your application for addition of products within a previously listed ARTG group has been approved and is now included with your current listing:

**AUST L:** 64615

**Product Number:** 1.125891  
2.147935  
3.147936

**Listing Name:** ATCOR MEDICAL PTY LTD BLOOD PRESSURE  
MEASURING DEVICES NON-STERILE  
{ATCOR MEDICAL WEST RYDE NSW, AUST}

A replacement certificate will be issued to you. These goods shall be listed subject to the conditions as stated in the Certificate of Listing related to this notification.

Further changes to this listing should be made in accordance with the TGA Publication, Device Requirements Version 4 (DR4), Appendix 3, 'Changes to Therapeutic Devices in the ARTG'. Information on the 'Conditions of Listing – Standard and Specific' are located at Appendix 4 of the DR4. The DR4 may be obtained from the TGA Publications Office, free call 1800 020 653 or via our web site at <http://www.health.gov.au/tga/docs/html/dr4.htm>.

Future communications regarding the products should include reference to the **Listing Number AUST L 64615**.

**Good Manufacturing Practice:** Where certificates of Good Manufacturing Practice/Conformity Assessment are provided they **must** be either an original certificate or a notarised copy. (Refer page 3 of the "Guidelines on Standard of Overseas Manufacturers – 12<sup>th</sup> Edition" which is available from the Publications Office, TGA, Telephone (02) 6232 8610.)



Delegate of the Secretary  
Device Listing Section  
Conformity Assessment Branch

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<sup>th.</sup>  
14 May 2001