

Australian Government

Department of Health Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Uscom Ltd

for approval to supply

Uscom Ltd - Sphygmomanometer, electronic, automatic

ARTG Identifier	227735
ARTG Start date	9/09/2014
Product Category	Medical Device Included Class IIa
GMDN	16173
GMDN Term	Automatic-inflation electronic sphygmomanometer, non-portable
Intended Purpose	BP+ is a non-invasive, compact standalone measurement device that automatically measures systolic and diastolic pressure, and pulse rate in adult and paediatric patients. BP+ also provides non-invasive central (aortic) systolic and diastolic blood pressure, augmentation index, pulse waveform and other parameters intended for use in adult patients. BP+ performs measurements using a conventional oscillometric method via a brachial cuff on the upper arm. The device is intended to be used under supervision by qualified healthcare personnel. The device is not intended for operating theatre, intensive care, or continuous patient monitoring use.

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

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. Sphygmomanometer, electronic, automatic

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: 227735 ARTG Start Date: 9/09/2014