

### **Department of Health**

Therapeutic Goods Administration

# **Australian Register of Therapeutic Goods Certificate**

Issued to

## **Team Medical Supplies Pty Ltd**

for approval to supply

# Team Medical Supplies Pty Ltd - Noninvasive ankle brachial pressure index measurement unit

ARTG Identifier 273748

ARTG Start date 2/04/2016

Product Category Medical Device Included Class IIa

**GMDN** 58928

GMDN Term Noninvasive ankle brachial pressure index measurement unit

Intended Purpose To non-invasively and automatically calculate, interpret, display and

print the ankle brachial pressure index of a patient along with pulse volume waveforms. This device consists of a control unit and cuffs

which are attached to the patient's arms and ankles.

Manufacturer Details	Address	Certificate number(s)
Huntleigh Healthcare Ltd Diagnostic Products Division	35 Portmanmoor Road , Cardiff, CF24 5HN United Kingdom	DV-2014-MC-20111-1

#### **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. Noninvasive ankle brachial pressure index measurement unit

**Product Specific Conditions** 

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