

## **Department of Health**

Therapeutic Goods Administration

# **Australian Register of Therapeutic Goods Certificate**

Issued to

## **Medical Equipment & Gases Australia**

for approval to supply

# Medical Equipment & Gases Australia - Regulator, gas, high-pressure

ARTG Identifier 144630

ARTG Start date 12/09/2007

Product Category Medical Device Included Class IIb

**GMDN** 35300

**GMDN Term** Regulator, gas, high-pressure

**Intended Purpose** Regulate the flow of a gas such as oxygen from a high pressure

cylinder, to a patient's face mask.

Manufacturer Details	Address	Certificate number(s)
Flotec	7625 West New York Street Indianapolis, IN, 46214 United States Of America	DV-20070803-MC-043409-11

#### **ARTG Standard Conditions**

The above Medical Device Included Class IIb 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. Regulator, gas, high-pressure

**Product Specific Conditions** 

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