



Australian Register of Therapeutic Goods Certificate

Issued to

MD Solutions Australasia Pty Ltd

for approval to supply

MD Solutions Australasia Pty Ltd - Analgesia unit, inhalation

ARTG Identifier	311931
ARTG Start date	27/11/2018
Product Category	Medical Device Included Class IIa
GMDN	16953
GMDN Term	Analgesia unit, inhalation
Intended Purpose	A kit intended for use with the Hand-Held Nitrous® Inhaler. It consists of the nitrous oxide cartridge and necessary nasal cannula or mask to provide the aerosolised gas for the patient to inhale.

Manufacturer Details	Address	Certificate number(s)
Strata Medical Innovations Inc	3706 76th Street Lubbock, Texas, 79423 United States Of America	DV-2018-MC-21378-1

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. Analgesia unit, inhalation

Product Specific Conditions

No specific conditions have been recorded against this entry.