



# 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

<b>ARTG Identifier</b>	311912
<b>ARTG Start date</b>	26/11/2018
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	16953
<b>GMDN Term</b>	Analgesia unit, inhalation
<b>Intended Purpose</b>	Hand Held Nitrous® is a nitrous oxide inhaler intended to create short term supplemental analgesia (pain and anxiety reduction) to patients undergoing minor medical procedures, exams and injections. Hand Held Nitrous® is for supplemental use only and to be used in addition to existing anesthetics only. It is not to be used as the sole source of analgesia or to modify existing analgesic protocols.

Manufacturer Details	Address	Certificate number(s)
Strata Medical Innovations Inc	3706 76th Street Lubbock, Texas, 79423 United States Of America	DV-2018-MC-15944-1

### 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.