



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

|                  |                                                                                                                                                                                                                                   |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Category | Medical Device Included Class IIa                                                                                                                                                                                                 |
| GMDN             | 60738                                                                                                                                                                                                                             |
| GMDN Term        | Endoscopic insufflation tubing set                                                                                                                                                                                                |
| Intended Purpose | The product is a 24 hour use with a gas filter to screen particles and keep fluid from flowing into CO2 source. The product is intended to be used with an CO2 source to supply CO2 to an endoscope during endoscopic procedures. |

## 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. Endoscopic insufflation tubing set

## Product Specific Conditions

No specific conditions have been recorded against this entry.

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