



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Smartline Medical Pty Ltd**

for approval to supply

## Smartline Medical Pty Ltd - Endoscope drying/storage chamber

<b>ARTG Identifier</b>	308798
<b>ARTG Start Date</b>	30/08/2018
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	45635
<b>GMDN Term</b>	Endoscope drying/storage chamber
<b>Intended Purpose</b>	A dedicated range of cabinets designed to dry and store flexible endoscopes in a clean storage environment that prevents bacterial growth after processing. Scopes are dried internally and externally by independently supplied clean HEPA filtered forced air. The cabinet is environmentally controlled to ensure scopes can be used directly without need for re-disinfection. The product is also equipped with clear doors (single door, pass through, or pass through X-Ray) and the option of either hooks or shelves to place several endoscopes. The product is approved for 31 days of continuous storage if an EN16442 model is selected.

Manufacturer Details	Address	Certificate number(s)
Smartline Medical Pty Ltd	55 Cordwell Road Off Industry Court YANDINA , QLD , 45 61 Australia	

### ARTG Standard Conditions

The above Medical Device Included Class 1 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. Endoscope drying/storage chamber

### Product Specific Conditions

No specific conditions have been recorded against this entry.