



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**InstruMED**

for approval to supply

## InstruMED - Speculum, <specify> - Speculum, <specify>

<b>ARTG Identifier</b>	305875
<b>ARTG Start Date</b>	29/06/2018
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	35517
<b>GMDN Term</b>	Speculum, <specify>
<b>Intended Purpose</b>	A surgical instrument which comprises two arms joined at a pivot point, and which is available in various sizes, shapes and contours. It has a blunt distal tip and is capable of expanding or stretching a lumen, body orifice or canal when inserted and opened. It is used for examination or the insertion of other instrumentation.

Manufacturer Details	Address	Certificate number(s)
Elcon Medical Instruments GmbH	Dr Karl-Storz-strasse 26A Tuttlingen , 78532 , Germany	

### 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. Speculum, <specify> - Speculum, <specify>

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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