



Australian Register of Therapeutic Goods Certificate

Issued to

InstruMED

for approval to supply

InstruMED - Speculum, rectal - Speculum, rectal

ARTG Identifier	305782
ARTG Start Date	29/06/2018
Product Category	Medical Device Included Class 1
GMDN	35351
GMDN Term	Speculum, rectal
Intended Purpose	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 used to expand or stretch the rectal orifice/canal when inserted and opened. It is used for examination or the insertion of other instrumentation. It is usually made of stainless steel. The portion of the arms proximal to the pivot point usually form the handle of the device while those distal to the pivot point open when force is exerted.

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, rectal - Speculum, rectal

Product Specific Conditions

No specific conditions have been recorded against this entry.