



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

InstruMED

for approval to supply

InstruMED - Speculum, vaginal, reusable - Speculum, vaginal, reusable

ARTG Identifier	305783
ARTG Start Date	29/06/2018
Product Category	Medical Device Included Class 1
GMDN	35352
GMDN Term	Speculum, vaginal, reusable
Intended Purpose	A device used during examination and treatment of the vagina for the purpose of providing access to the interior, usually by expanding/distending the opening to this orifice. This device may be designed with adjustable or fixed blades and may have built-in lighting, e.g. a fiberoptic bundle. The device can be made of metal or durable plastics. This device is reusable after sterilization.

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, vaginal, reusable - Speculum, vaginal, reusable

Product Specific Conditions

No specific conditions have been recorded against this entry.

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