



Australian Register of Therapeutic Goods Certificate

Issued to

InstruMED

for approval to supply

InstruMED - Cervical dilator, fixed-size

ARTG Identifier	305639
ARTG Start Date	29/06/2018
Product Category	Medical Device Included Class 1
GMDN	11266
GMDN Term	Cervical dilator, fixed-size
Intended Purpose	A hand-held manual surgical instrument designed to dilate the common bile duct, i.e., the union of the cystic and hepatic ducts. It typically consists of a slender hollow or solid body instrument in a cylindrical form. It is available in a variety of sizes (diameters) and flexibilities. This is a reusable device.

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. Cervical dilator, fixed-size

Product Specific Conditions

No specific conditions have been recorded against this entry.