



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 329426 AMALGAMATED INSTRUMENT GROUP PTY LTD - General/multiple surgical laser system beam guide, single-use

**ARTG entry for** Medical Device Included Class IIa  
**Sponsor** AMALGAMATED INSTRUMENT GROUP PTY LTD  
**Postal Address** Unit 5/28 Leighton Place, Hornsby, NSW, 2077  
Australia  
**ARTG Start Date** 4/02/2020  
**Product Category** Medical Device Class IIa  
**Status** Active  
**Approval Area** Medical Devices

### 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.

### Manufacturers

Name	Address
Asclepion Laser Technologies GmbH	Brusseler Strasse 10 Jena, , 07747 Germany

### Products

#### 1 . General/multiple surgical laser system beam guide, single-use

Product Type	Single Device Product	Effective Date	4/02/2020
<b>GMDN</b>	62600 General/multiple surgical laser system beam guide, single-use		
<b>Intended Purpose</b>	The optical fibers are used in conjunction with lasers, as laser beam transmission system. The indications depend on the device the fibers are used with.		

### Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary