



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	400350	Life Healthcare Pty Ltd - General/multiple surgical laser system beam guide, single-use
ARTG entry for	Medical Device Included Class IIb	
Sponsor	Life Healthcare Pty Ltd	
Postal Address	PO Box 646, NORTH RYDE, NSW, 2113 Australia	
ARTG Start Date	30/11/2022	
Product Category	Medical Device Class IIb	
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
EMS Electro Medical Systems SA	Chemin De La Vuarpilliere 31 NYON, 1260, Switzerland

Products

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

Product Type	Single Device Product	Effective Date	30/11/2022
GMDN	62600 General/multiple surgical laser system beam guide, single-use		
Intended Purpose	Surgical Laser Fibers (surgical fiber optic laser delivery devices) are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT/otolaryngology, also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumours and lesions, complete or partial resection of internal organs, tumours or lesions, tissue vaporization, haemostasis, lithotripsy and/or coagulation may be indicated with an approved compatible laser. Surgical Laser Fibers are indicated for use with laser devices emitting radiation from 532-2100 nm, with pulsed & continuous wave(CW) emission modes ie compatible for use with Diode lasers, Argon, KTP/532, Ho:YAG, Nd:YAG, Tm:YAG pulsed & CW lasers.		

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