



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 285968 Alpha Mobility Solutions Trust - Surgical diode laser system

ARTG entry for Medical Device Included Class IIb
Sponsor Alpha Mobility Solutions Trust
Postal Address 27 Oakbank Terrace, Murwillumbah, NSW, 2484
Australia
ARTG Start Date 21/02/2017
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
Eltech K-Laser SRL	Via Castagnole 20/H - Interno 2 , Treviso, 31100 Italy

Products

1 . Surgical diode laser system

Product Type	Single Device Product	Effective Date	21/02/2017
GMDN	60341 Surgical diode laser system		
Intended Purpose	Laser devices indicated for muscular and skeletal pathologies, osteoarticular diseases, edemas, soft tissue injuries and laser acupuncture. With the specific hand-pieces it can be used for benign skin disease, pigmented and vascular lesions and acne vulgaris. Also used for incision, coagulation and homeostasis of soft tissue in medical specialties including ENT, Dermatology, Cosmetic and Gynecology.		

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