



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 323941 Alma Lasers Australia Pty Ltd - Dermatological carbon dioxide laser system

ARTG entry for Medical Device Included Class IIb
Sponsor Alma Lasers Australia Pty Ltd
Postal Address G01 184 Bourke Road, Alma Lasers, Alexandria, NSW, 2015
Australia
ARTG Start Date 23/09/2019
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
Alma Lasers GmbH	Nordostpark 100-102 , Nuernberg, 90411 Germany

Products

1 . Dermatological carbon dioxide laser system

Product Type	Single Device Product	Effective Date	23/09/2019
GMDN	61473 Dermatological carbon dioxide laser system		
Intended Purpose	intended to incise, excise, ablate, coagulate and vaporize for dermatological and soft tissue applications.		

Specific Conditions

No Specific Conditions included on Record

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