



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	368270	Alma Lasers Australia Pty Ltd - 308 Excimer - Ultraviolet phototherapy unit
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	4/06/2021	
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 . 308 Excimer - Ultraviolet phototherapy unit

Product Type	Medical device system	Effective Date	4/06/2021
GMDN	35149 Ultraviolet phototherapy unit		
Intended Purpose	An ultraviolet excimer system indicated for dermatological procedures for the treatment of psoriasis and vitiligo on the body. The device is intended to be used to selectively treat the indications. The lamp is a xenon-chloride excimer lamp with a wavelength of 308 nanometres. Its output power is 800 mW \pm 10% for 2.48 \times 2 (16 cm ²). It is computer controlled, and displays the treatment parameters.		

Specific Conditions

No Specific Conditions included on Record

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