

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334086	Ultimate Dental Supplies - Denture base resin, cured	
ARTG entry for	Medical Device Included Class IIa		
Sponsor	Ultimate Denta	Itimate Dental Supplies	
Postal Address	660A South Ro Australia	60A South Road, MOORABBIN, VIC, 3189 .ustralia	
ARTG Start Date	14/04/2020		
Product category	Medical Device	cal 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

Mycone Dental Supply Co Inc

Address 52 West King Street Myerstown, PA, 17067 United States Of America

Products

Pro	aucts			
1. Denture base resin, cured				
	Product Type	Single Device Product	Effective date	14/04/2020
	GMDN	16730 Denture base resin, cured Bio-compatible materials for manufacturing splints, night guards, retainers and full or partial denture		
	Intended purpose			
	Specific Conditions			

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