



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 357996 Ampac Dental - Light, dental, general-purpose

ARTG entry for Medical Device Included Class 1

Sponsor Ampac Dental

Postal Address PO Box 554, ROCKDALE, NSW, 2216
Australia

ARTG Start Date 26/03/2021

Product Category Medical Device Class 1

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
Faro SPA	Via Faro 15-20060 Organo, Milano, 0 Italy

Products

1 . Light, dental, general-purpose

Product Type	Effective Date
Single Device Product	26/03/2021

GMDN 12351 Light, dental, general-purpose

Intended Purpose This is a dedicated light that is intended to be used designed for general-purpose dental use that delivers intense focused lighting to the dental operating, examination, procedure site, during dental procedures in the mouth.

Specific Conditions

No Specific Conditions included on Record

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