



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

DIO Australia Pty Ltd

for approval to supply

**DIO Australia Pty Ltd - Dental implant suprastructure device,
permanent**

ARTG Identifier	396752
ARTG Start Date	30/09/2022
Product Category	Medical Device Included Class IIb
GMDN	44879
GMDN Term	Dental implant suprastructure device, permanent
Intended Purpose	The abutments are placed into a dental implant to provide support for a prosthetic reconstruction. Used by licensed dentist, abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patients. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. It is not recommended for patients with incomplete jaw growth. This is in contact with tissue and is used for a long term.

Manufacturer Details	Address	Certificate number(s)
DIO Corporation	66 Centum seo-ro Haeundae-gu , Busan , 48058 Korea - Republic of	DV-2021-MC-01041-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Dental implant suprastructure device, permanent

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 396752
ARTG Start Date: 30/09/2022