

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 445501 PERTH DENTAL SUPPLIES PTY LTD - Screw endosteal dental implant, two-piece

ARTG entry for Medical Device Included Class IIb

Sponsor PERTH DENTAL SUPPLIES PTY LTD

Postal Address PO Box 571, Balcatta, WA, 6914

Australia

ARTG Start Date 8/04/2024

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 (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

MSDI Medical Systems and Devices

International Ltd

Derech Haifa 37 PO Box 25414

, Kiryat Ata, 2822639

Israel

Products

1 . Screw endosteal dental implant, two-piece

Product Type Single Device Product Effective Date 8/04/2024

GMDN 55849 Screw endosteal dental implant, two-piece

Intended Purpose Surgical restorative application for placement in the bone of the upper and lower jaw, to provide support of prosthetic devices, such

as artificial teeth

Specific Conditions

No Specific Conditions included on Record

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