



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	300125	Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Screw endosteal dental implant, one-piece
ARTG entry for	Medical Device Included Class IIb	
Sponsor	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	
Postal Address	Level 20 Tower II Darling Park 201 Sussex Street, SYDNEY, NSW, 2000 Australia	
ARTG Start Date	27/02/2018	
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
CeraRoot SL	Parpers 13 Les Franqueses del Valles Catalonia, Barcelona, 08520 Spain

Products

1 . Screw endosteal dental implant, one-piece

Product Type	Single Device Product	Effective Date	27/02/2018
GMDN	55848 Screw endosteal dental implant, one-piece		
Intended Purpose	The dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function.		

Specific Conditions

No Specific Conditions included on Record

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