



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

**Public Summary**

<b>Summary for ARTG Entry:</b>	300125	Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Screw endosteal dental implant, one-piece
<b>ARTG entry for</b>	Medical Device Included Class IIb	
<b>Sponsor</b>	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	
<b>Postal Address</b>	Level 20 Tower II Darling Park 201 Sussex Street, SYDNEY, NSW, 2000 Australia	
<b>ARTG Start Date</b>	27/02/2018	
<b>Product category</b>	Medical Device Class IIb	
<b>Status</b>	Active	
<b>Approval area</b>	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	Joseph Umbert 128 Granollers , Barcelona, 08402 Spain

**Products**

**1. Screw endosteal dental implant, one-piece**

<b>Product Type</b>	Single Device Product	<b>Effective date</b>	27/02/2018
<b>GMDN</b>	55848 Screw endosteal dental implant, one-piece		
<b>Intended purpose</b>	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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