



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

## Public Summary

<b>Summary for ARTG Entry:</b>	314894	Bioconcept Australia Pty Ltd - Screw endosteal dental implant, two-piece
<b>ARTG entry for</b>	Medical Device Included Class IIb	
<b>Sponsor</b>	Bioconcept Australia Pty Ltd	
<b>Postal Address</b>	Level 26 44 Market Street, Sydney, NSW, 2000 Australia	
<b>ARTG Start Date</b>	27/02/2019	
<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
Bio Concept Co Ltd	Unit C No 26 Huashan Middle Road Xinbei Zone Changzhou Jiangsu, China, 213022 China

### Products

#### 1 . Screw endosteal dental implant, two-piece

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	27/02/2019
<b>GMDN</b>	55849 Screw endosteal dental implant, two-piece		
<b>Intended Purpose</b>	This is a sterile device that is intended to be surgically implanted into alveolar and/or basal bone of the mandible or maxilla to provide support and a means of retention for a dental prosthesis. It is classified as a two-piece device composed of an anchorage component (implant body) being a threaded screw that is implanted into bone, and a retention component (implant abutment)		

### Specific Conditions

No Specific Conditions included on Record

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