



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	315110	Bioconcept Australia Pty Ltd - Drill bit, surgical
ARTG entry for	Medical Device Included Class IIa	
Sponsor	Bioconcept Australia Pty Ltd	
Postal Address	Level 26 44 Market Street, Sydney, NSW, 2000 Australia	
ARTG Start Date	5/03/2019	
Product Category	Medical Device Class IIa	
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
Bio Concept Co Ltd	Unit C No 26 Huashan Middle Road Xinbei Zone Changzhou Jiangsu, China, 213022 China

Products

1 . Drill bit, surgical			
Product Type	Single Device Product	Effective Date	5/03/2019
GMDN	32390 Drill bit, surgical		
Intended Purpose	This is a device that is intended to be mounted into a surgical drilling machine, that, when rotated at the appropriate speed, will cut into bone creating a hole of the same dimension as the diameter of the bit. To be used during dental procedures in the mouth.		

Specific Conditions

No Specific Conditions included on Record

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