



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Bioconcept Australia Pty Ltd

for approval to supply

Bioconcept Australia Pty Ltd - Screw endosteal dental implant, two-piece

ARTG Identifier	314894
ARTG Start date	27/02/2019
Product Category	Medical Device Included Class IIb
GMDN	55849
GMDN Term	Screw endosteal dental implant, two-piece
Intended Purpose	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)

Manufacturer Details	Address	Certificate number(s)
Bio Concept Co Ltd	Unit C No 26 Huashan Middle Road Xinbei Zone Changzhou Jiangsu, China, 213022 China	DV-2019-MC-01795-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Screw endosteal dental implant, two-piece

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 314894
ARTG Start Date: 27/02/2019



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**Bioconcept Australia Pty Ltd - Saw blade, surgical, powered,
reciprocating**

ARTG Identifier	315111
ARTG Start date	5/03/2019
Product Category	Medical Device Included Class IIa
GMDN	44985
GMDN Term	Saw blade, surgical, powered, reciprocating
Intended Purpose	This is a flat metal surgical instrument, that has serrated edge that is intended to be attachment to a dedicated powered surgical that is intended to be used for cutting bone/tissue when a directional pressure is applied during dental procedures in the mouth.

Manufacturer Details	Address	Certificate number(s)
Bio Concept Co Ltd	Unit C No 26 Huashan Middle Road Xinbei Zone Changzhou Jiangsu, China, 213022 China	DV-2019-MC-01795-1

ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Saw blade, surgical, powered, reciprocating

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 315111
ARTG Start Date: 5/03/2019



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Bioconcept Australia Pty Ltd - Drill bit, surgical

ARTG Identifier	315110
ARTG Start date	5/03/2019
Product Category	Medical Device Included Class IIa
GMDN	32390
GMDN Term	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.

Manufacturer Details	Address	Certificate number(s)
Bio Concept Co Ltd	Unit C No 26 Huashan Middle Road Xinbei Zone Changzhou Jiangsu, China, 213022 China	DV-2019-MC-01795-1

ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Drill bit, surgical

Product Specific Conditions

No specific conditions have been recorded against this entry.