



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Dental Axess Pty Ltd

for approval to supply

Dental Axess Pty Ltd - Dental ceramic

ARTG Identifier	260210
ARTG Start date	22/09/2015
Product Category	Medical Device Included Class IIa
GMDN	16187
GMDN Term	Dental ceramic
Intended Purpose	This is an ingot of material that is a zirconium oxide ceramic-based material that is intended to be used for to prefabricate devices used in the mouth during dental restorative procedures.

Manufacturer Details	Address	Certificate number(s)
Doceram Medical Ceramics GmbH	Hesslingsweg 65-67 Dortmund, , D-44309 Germany	DV-2015-MC-14701-1

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. Dental ceramic

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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