



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Kulzer Australia Pty Ltd

for approval to supply

Kulzer Australia Pty Ltd - Dental crown/bridge resin, temporary

ARTG Identifier	383571
ARTG Start Date	7/02/2022
Product Category	Medical Device Included Class IIa
GMDN	45236
GMDN Term	Dental crown/bridge resin, temporary
Intended Purpose	This is a C&B temp is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges. The fabricated temporary crowns or bridges are an alternative to preformed temporary crowns or bridges. The fabrication of temporary crowns or bridges with dima Print C&B temp requires digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment

Manufacturer Details	Address	Certificate number(s)
Dentca Inc	357 Van Ness Way Suite 250 Torrance , CA , 9050 1 United States Of America	DV-2022-MC-01067-1

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 crown/bridge resin, temporary

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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