



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 - Denture base resin, cured

ARTG Identifier	383305
ARTG Start Date	1/02/2022
Product Category	Medical Device Included Class IIa
GMDN	16730
GMDN Term	Denture base resin, cured
Intended Purpose	This is a light-curable resin that is intended to be used for fabrication and repair of full and partial removable dentures and base plates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with dima Print Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system.

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. Denture base resin, cured

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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