



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 393032 Vatech Medical Pty Ltd - Dental ceramic

<b>ARTG entry for</b>	Medical Device Included Class IIa
<b>Sponsor</b>	Vatech Medical Pty Ltd
<b>Postal Address</b>	Suite 5.04 Gateway Business Park, 63-79 Parramatta Road, Silverwater, NSW, 2128 Australia
<b>ARTG Start Date</b>	28/07/2022
<b>Product Category</b>	Medical Device Class IIa
<b>Status</b>	Active
<b>Approval Area</b>	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**

<b>Name</b>	<b>Address</b>
Vatechacucera Inc	C-dong 2544 Nambuk-daero Idongeup Cheoin-gu Yongin-si , Gyeonggi-do, 17138 Korea - Republic of

**Products**

**1 . Dental ceramic**

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	28/07/2022
<b>GMDN</b>	16187 Dental ceramic		
<b>Intended Purpose</b>	This is a ceramic-based of material that is intended to be used to prefabricated and custom-made dental restorations to used in the mouth during dental procedures such as the production of inlays, artificial teeth, metal-ceramic crowns, or bridges.		

**Specific Conditions**

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary