



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 455886 VTS Dental Pty Ltd - Denture, <specify>

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** VTS Dental Pty Ltd  
**Postal Address** 1/333 Canterbury Road, Canterbury, NSW, 2193  
Australia  
**ARTG Start Date** 22/07/2024  
**Product Category** Medical Device Class 1  
**Status** Active  
**Approval Area** 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

Name	Address
VTS Dental Pty Ltd	1/333 Canterbury Road Canterbury, NSW, 2193 Australia

### Products

#### 1 . Denture, <specify>

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	22/07/2024
<b>GMDN</b>	38587 Denture, <specify>		
<b>Intended Purpose</b>	The device is intended to be used to replace a patient's missing teeth for functional and/or aesthetic reasons. The device is removable and intended for single patient use.		

### Specific Conditions

No Specific Conditions included on Record

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Public Summary



Australian Government

Department of Health and Aged Care  
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# Australian Register of Therapeutic Goods Certificate

Issued to

**VTS Dental Pty Ltd**

for approval to supply

**VTS Dental Pty Ltd - Denture, <specify>**

<b>ARTG Identifier</b>	458926
<b>ARTG Start Date</b>	8/08/2024
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	38587
<b>GMDN Term</b>	Denture, <specify>
<b>Intended Purpose</b>	A removable artificial replacement for one or more teeth carried on a removable plate or frame. A denture is custom-made in a variety of forms, e.g. replacing all or some teeth; shapes and materials, e.g. polymers, acrylic, ceramic or metal, e.g. base metal alloys or titanium.

Manufacturer Details	Address	Certificate number(s)
Next Lab Company Ltd	118/33A Huynh Thien Loc Street Hoa Thanh Ward Tan Phu District, Ho Chi Minh City, Vietnam	

## ARTG Standard Conditions

The above Medical Device Included Class 1 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, <specify>

## 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: 458926  
ARTG Start Date: 8/08/2024



Australian Government

Department of Health and Aged Care  
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# Australian Register of Therapeutic Goods Certificate

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**VTS Dental Pty Ltd**

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## VTS Dental Pty Ltd - Dental occlusal splint, custom-made

<b>ARTG Identifier</b>	463085
<b>ARTG Start Date</b>	30/09/2024
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	43025
<b>GMDN Term</b>	Dental occlusal splint, custom-made
<b>Intended Purpose</b>	A rigid or flexible custom-made device intended to overlay the occlusal surfaces of the teeth to maintain the position of displaced or moveable teeth, to treat teeth clenching and bruxism and their sequelae, and to provide temporary relief from muscle or temporomandibular joint (TMJ) pain (e.g., from TMJ dysfunction). It is typically made of synthetic polymer materials and manufactured to meet the needs of an individual patient.

Manufacturer Details	Address	Certificate number(s)
VTS Dental Pty Ltd	1/333 Canterbury Road Canterbury , NSW , 2 193 Australia	

### ARTG Standard Conditions

The above Medical Device Included Class 1 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 occlusal splint, custom-made

### 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](mailto:info@tga.gov.au)

ARTG Identifier: 463085  
ARTG Start Date: 30/09/2024



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**VTS Dental Pty Ltd**

for approval to supply

## VTS Dental Pty Ltd - Dental occlusal splint, custom-made

<b>ARTG Identifier</b>	463086
<b>ARTG Start Date</b>	30/09/2024
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	43025
<b>GMDN Term</b>	Dental occlusal splint, custom-made
<b>Intended Purpose</b>	A rigid or flexible custom-made device intended to overlay the occlusal surfaces of the teeth to maintain the position of displaced or moveable teeth, to treat teeth clenching and bruxism and their sequelae, and to provide temporary relief from muscle or temporomandibular joint (TMJ) pain (e.g., from TMJ dysfunction). It is typically made of synthetic polymer materials and manufactured to meet the needs of an individual patient. This is a reusable device.

Manufacturer Details	Address	Certificate number(s)
Next Lab Company Ltd	118/33A Huynh Thien Loc Street Hoa Thanh Ward Tan Phu District , Ho Chi Minh City , Vietnam	

### ARTG Standard Conditions

The above Medical Device Included Class 1 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 occlusal splint, custom-made

### 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](mailto:info@tga.gov.au)

ARTG Identifier: 463086  
ARTG Start Date: 30/09/2024