



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**VNS Dental Lab**

for approval to supply

## VNS Dental Lab - Dental occlusal splint, custom-made

|                         |  |
|-------------------------|--|
| <b>ARTG Identifier</b>  | 464590   |
| <b>ARTG Start Date</b>  | 15/10/2024   |
| <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 pain. 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) |
|----------------------|--|-----------------------|
| VNS Dental Lab       | Shop 1 375 Crown Street<br>Wollongong , NSW ,<br>2500<br>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: 464590  
ARTG Start Date: 15/10/2024



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

|                         |   |
|-------------------------|---|
| <b>Record Summary</b>   | 464606 VNS Dental Lab - Dental occlusal splint, custom-made |
| <b>Sponsor</b>          | VNS Dental Lab  |
| <b>Therapeutic Type</b> | Medical Device  |
| <b>Product Category</b> | Included Class 1  |
| <b>ARTG Start Date</b>  | 15/10/2024  |
| <b>Postal Address</b>   | Shop 1 375 Crown Street, Wollongong, NSW, 2500<br>Australia |
| <b>Billing Address</b>  | Shop 1 375 Crown Street, Wollongong, NSW, 2500<br>Australia |
| <b>Product Type</b>     | Medical Device - Class 1 - Included                         |
| <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**

| Name                 | Address   | Certificate number(s) |
|----------------------|---|-----------------------|
| Next Lab Company Ltd | 118/33A Huynh Thien Loc Street Hoa Thanh Ward<br>Tan Phu District , Ho Chi Minh City ,<br>Vietnam |                       |

**Products**

**1 . Dental occlusal splint, custom-made**

|                     |                       |                       |            |
|---------------------|-----------------------|-----------------------|------------|
| <b>Product Type</b> | Single Device Product | <b>Status</b>         | Current    |
|                     |                       | <b>Effective Date</b> | 15/10/2024 |

**GMDN** 43025 Dental occlusal splint, custom-made  
**Functional Description** Not included on record  
**Intended Purpose** 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. It is typically made of synthetic polymer materials and manufactured to meet the needs of an individual patient. This is a reusable device.

**Variant Information**

**Device Information**

03 Dental devices

**Specific Conditions**

No Specific Conditions included on Record

Record Summary