



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

# Australian Register of Therapeutic Goods Certificate

Issued to

**Durodent Holdings Pty Ltd**

for approval to supply

**Durodent Holdings Pty Ltd - Dental material, <specify>**

<b>ARTG Identifier</b>	293622
<b>ARTG Start date</b>	7/09/2017
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	40592
<b>GMDN Term</b>	Dental material, <specify>
<b>Intended Purpose</b>	UV light cured material used for forming and fabricating dental devices including special impression trays used to take an impressions, functional trays, custom trays, bite-blocks, registration bite plates. It is inserted for a short period of time in a patients mouth or for other uses in the dental laboratory.

Manufacturer Details	Address	Certificate number(s)
Ernst Hinrichs Dental Gmbh	Borsigstr 1 , Goslar, D-38644 Germany	

## 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 material, <specify>**

## Product Specific Conditions

.

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: 293622  
ARTG Start Date: 7/09/2017