



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>

ARTG Identifier	293623
ARTG Start date	7/09/2017
Product Category	Medical Device Included Class 1
GMDN	40592
GMDN Term	Dental material, <specify>
Intended Purpose	Thermal formable plastic sheets that are used to form a temporary dental devices including PVC splints, Retainers, base plates, PETG splints for temporary crown and bridge, soft EVA's / mouth guards and custom trays to be placed in patients mouths on a temporary short term basis.

Manufacturer Details	Address	Certificate number(s)
Keystone Industries	52 West King Street Myerstown , PA, 17067 United States Of America	

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

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Therapeutic Goods Administration
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