



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 - Denture clasp, metal, custom-made

ARTG Identifier	311410
ARTG Start date	12/11/2018
Product Category	Medical Device Included Class 1
GMDN	42879
GMDN Term	Denture clasp, metal, custom-made
Intended Purpose	Includes a range metal products including preformed dental clasps, retaining wire, strengtheners, mesh and lingual bars that is used in the manufacture of removable dental devices like partial dentures, full dentures and orthodontic device. These products help with retention and strength of the device within the patients mouth.

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. Denture clasp, metal, 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

ARTG Identifier: 311410
ARTG Start Date: 12/11/2018