

**TGA (Therapeutic Goods Australia)  
Sponsor Registrations For Medical Devices  
General Advice Letter**



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To Whom It May Concern,

**RE: Durodent ARTG (Australian Register of Therapeutic Goods) Sponsor Registration Certificates**

Durodent Holdings Pty Ltd, trading as “**Durodent Dental Supplies**” is a registered sponsor with the TGA (Therapeutic Goods Australia).

All products classed as a “Medical Device” that are supplied by “Durodent Dental Supplies” in Australia are registered with **Therapeutic Goods Administration (TGA)**.

ARTG registrations are held by the primary importer (sponsor) of the product / medical device supply in Australia.

For example:

1. **Kulzer brand** products ARTG certificates are held by **Kulzer Australia** – All Australian dealers are covered by these.
2. **Cavex brand** products ARTG certificates are held by **W9 Australia** – All Australian dealers are covered by these.
3. **Zhermack brand** products ARTG certificates are held by **Durodent Holdings Pty Ltd** – as we are the direct importer of these products.

ARTG registrations are applicable to products / product categories classed as a “Medical Device”.

ARTG registrations do not mention brand names (eg. Kulzer Pala or Kulzer Delara) but are registered based on products Global Medical Device Nomenclature (GMDN) categories codes. For example Kulzer “Denture Acrylics” (Known as brand names: Paladon 65, PalaXpress) are listed using **GMDN category code “16728 Dental material, denture base, polymer based”**.

Multiple related products from one manufacture are covered by one registered ARTG Certificate for the related Manufacturer / Product Category

Durodent ARTG certificates can be found and sourced:

1. **Durodent Website** - Durodent website under “Downloads” > “TGA Registration and ARTG Certificates” tab. <https://www.durodent.com.au/downloads>
2. **TGA Website** – ARTG Search and download by Sponsor (Importer) / Manufacturer / GMDN (eg. 38643 Artificial teeth, resin).
  - a. **Durodent Holding Pty Ltd Sponsor Specific ARTG Search Link:**
    - i. <https://www.tga.gov.au/resources/artg?keywords=Durodent+Holdings>
  - b. **Access and search all ARTG certificates and details at**
    - i. <https://compliance.health.gov.au/artg/>

To request any other required details directly from our customer service team at [office@durodent.com.au](mailto:office@durodent.com.au)

Kind Regards,

Durodent Dental Supplies