



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Durodent Holdings Pty Ltd**

for approval to supply

**Durodent Holdings Pty Ltd - Bath, ultrasonic cleaning unit**

<b>ARTG Identifier</b>	419492
<b>ARTG Start Date</b>	23/08/2023
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	36749
<b>GMDN Term</b>	Bath, ultrasonic cleaning unit
<b>Intended Purpose</b>	An ultrasonic cleaning device used for pre-cleaning and cleaning dental appliances, objects, instruments and materials submerged in cleaning fluid using ultrasonic waves transmitted through a medium e.g. water. The cleaning effect is produced by the physical action of the ultrasound generated by the unit. The cleaning power can be boosted by adding suitable cleaning agents and by increasing the temperature and duration of the bath. The unit is also authorised for use in typical laboratory applications. Used with original accessories manufactured for the unit.

Manufacturer Details	Address	Certificate number(s)
Elma Schmidbauer GmbH	Gottlieb-Daimler-Str 17 , Singen , D-78224 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. Bath, ultrasonic cleaning unit

## Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
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