



Australian Register of Therapeutic Goods Certificate

Issued to

Amplitude Australia Pty Ltd

for approval to supply

Amplitude Australia Pty Ltd - Orthopaedic reamer, bone resection

ARTG Identifier	529220
ARTG Start Date	22/07/2026
Product Category	Medical Device Included Class IIa
GMDN	45114
GMDN Term	Orthopaedic reamer, bone resection
Intended Purpose	Reusable, non-sterile cutting tool intended to cut and shape bone in the implantation of joint prostheses. They may be rotated by hand or connected to a power tool.

Manufacturer Details	Address	Certificate number(s)
Sayan Tibbi Aletler Pazarlama San ve Tic Ltd Sti	Kemalpasa Mahallesi 7110/2 Sokak No 4 Bornova, Izmir, 35060 Turkey	DV-2026-MC-16300-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Orthopaedic reamer, bone resection

Product Specific Conditions

No specific conditions have been recorded against this entry.