



Australian Government

Department of Health
Therapeutic Goods Administration

| | | |
|-------------------------|--|--|
| Record Summary | 230964 | Precise Medical Supplies Pty Ltd - Sagittal surgical saw blade, single-use |
| Sponsor | Precise Medical Supplies Pty Ltd | |
| Therapeutic Type | Medical Device | |
| Product Category | Included Class IIa | |
| ARTG Start date | 22/11/2014 | |
| Postal Address | PO Box 421, Paddington, NSW, 2021 Australia | |
| Billing Address | PO Box 421, Paddington, NSW, 2021 Australia | |

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.

Manufacturers

| Name | Address | Certificate number(s) |
|----------------------------|--|------------------------------|
| Omega Surgical Instruments | G-8305 South Saginaw Street GRAND BLANC, MICHIGAN, 48439 United States Of America | |

Products

1.Sagittal surgical saw blade, single-use

| | | | |
|---------------------|-----------------------|-----------------------|------------|
| Product Type | Single Device Product | Status | Current |
| | | Effective date | 22/11/2014 |

| | |
|-------------------------------|--|
| GMDN | 43376 Sagittal surgical saw blade, single-use |
| Functional description | Not included on record |
| Intended purpose | used for cutting bone/tissue during orthopaedic/oral surgery |

Variant information

Device Information

- 07 Non-active implantable devices
- 03 Dental devices
- 04 Electro mechanical medical devices

Specific Conditions

Record Summary