



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|---|
| Summary for ARTG Entry: | 334601 | Ironbark Creek Investments - Mask, surgical, single use |
| ARTG entry for | Medical Device Included Class 1 | |
| Sponsor | Ironbark Creek Investments | |
| Postal Address | Po Box 142, Warners Bay, NSW, 2282 Australia | |
| ARTG Start Date | 19/04/2020 | |
| Product Category | Medical Device Class 1 | |
| Status | Active | |
| Approval Area | Medical Devices | |

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 |
|------|---------|
|------|---------|

Products

1 . Mask, surgical, single use

| | | | |
|-------------------------|---|-----------------------|------------|
| Product Type | Single Device Product | Effective Date | 19/04/2020 |
| GMDN | 35177 Mask, surgical, single use | | |
| Intended Purpose | Used by medical personnel to cover the nose and mouth to prevent the transmission of airborne organisms while surgery is being performed. | | |

Specific Conditions

No Specific Conditions included on Record

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