



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 342538 MYKL Pty Ltd - Mask, surgical, single use

ARTG entry for Medical Device Included Class 1
Sponsor MYKL Pty Ltd
Postal Address PO Box 8092, Kooyong, VIC, 3144
Australia
ARTG Start Date 28/08/2020
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 |
|---------------------------|---|
| Sunlight Eco-tech Limited | Unit D 2/F Speedy Industrial Building 114 How Ming Street Kwun Tong, KLN, Hong Kong - SAR of China |

Products

1 . Mask, surgical, single use

| | | | |
|-------------------------|---|-----------------------|------------|
| Product Type | Single Device Product | Effective Date | 28/08/2020 |
| GMDN | 35177 Mask, surgical, single use | | |
| Intended Purpose | Disposable single-use surgical mask to be placed over the nose and mouth of the wearer to prevent the transmission of airborne organisms. | | |

Specific Conditions

No Specific Conditions included on Record

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