



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 333133 M House Pty Ltd - Mask, surgical, single use

ARTG entry for Medical Device Included Class 1

Sponsor M House Pty Ltd

Postal Address 1/46 Jacka Street, Macleod, VIC, 3085
Australia

ARTG Start Date 1/04/2020

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
Wuhan Topmed Trading Co	1904-1905 Block D Future City NO 147 South of Luoshi Road Hongshan District Wuhan, Hubei, 430070 China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	1/04/2020
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GMDN 35177 Mask, surgical, single use

Intended Purpose A single-use device intended to be placed over the nose and mouth of a person to prevent the transmission of microbial organisms through transmission vectors. It is made of a flexible, porous fabric material that enables the user to breathe normally through the mask.

Specific Conditions

No Specific Conditions included on Record

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