



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 341028 Stonestar Wholesale Pty Ltd - Mask, surgical, single use

ARTG entry for Medical Device Included Class 1

Sponsor Stonestar Wholesale Pty Ltd

Postal Address 305 Boundary Road, Mordialloc, VIC, 3195
Australia

ARTG Start Date 6/08/2020

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
Yi Ting Non-Woven Co Ltd	No 66-2 Wenming Road Guishan District, Taoyuan City, 33382 Taiwan

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	6/08/2020
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GMDN 35177 Mask, surgical, single use

Intended Purpose To be worn over nose & mouth during medical or surgical procedures to prevent bi-directional flow of micro-organisms

Specific Conditions

No Specific Conditions included on Record

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