



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 340235 Cleanstar Pty Ltd - Mask, surgical, single use

ARTG entry for Medical Device Included Class 1

Sponsor Cleanstar Pty Ltd

Postal Address 59 Radford Road, Reservoir, VIC, 3073
Australia

ARTG Start Date 27/07/2020

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
Phu Bao Medical	Lot C21 D2 Street Cau Tram Industrial Park Long Trach Commune Can Duoc Ward, Long An Province, Vietnam

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	27/07/2020
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GMDN 35177 Mask, surgical, single use

Intended Purpose Loose-fitting, disposable face masks designed to create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. They are used to reduce the chance of spreading airborne diseases and prevent airborne dust particles created by air pollution. The face masks are manifold in patterns, colors, which are comfortable and suitable for medical, clinical, industrial chemical, heavy metal exploitation, and daily use purpose

Specific Conditions

No Specific Conditions included on Record

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