



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 339903 Ktena Knitting Pty Ltd - Airway protection face mask

ARTG entry for Medical Device Included Class 1

Sponsor Ktena Knitting Pty Ltd

Postal Address 20 Burlington Street, Oakleigh, VIC, 3166
Australia

ARTG Start Date 21/07/2020

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
Ktena Knitting Pty Ltd	20 Burlington Street Oakleigh, VIC, 3166 Australia

Products

1 . Airway protection face mask

Product Type	Single Device Product	Effective Date	21/07/2020
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GMDN 18094 Airway protection face mask

Intended Purpose placed over the nose and mouth to provide respiratory protection from dust, mists, and other airborne particles

Specific Conditions

No Specific Conditions included on Record

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