



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 236803 Aero Healthcare - Mask, resuscitation

ARTG entry for Medical Device Included Class 1

Sponsor Aero Healthcare

Postal Address

ARTG Start Date 29/04/2015

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	Location Id
Aero Health Aust Pty Ltd T/A Aero Healthcare (Australia)		145771

Products

1 . Mask, resuscitation

Product Type Single Device Product **Effective Date** 29/04/2015

GMDN 36066 Mask, resuscitation

Intended Purpose A malleable cone placed over the nose and mouth to administer air to a patient during cardiopulmonary resuscitation (CPR). The device is designed to replace mouth-to-mouth resuscitation therefore avoiding cross contamination; it is also used on manikins during CPR training. The device may include an airway, one-way valve or other component.

Specific Conditions

No Specific Conditions included on Record

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