



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	314855	O&M Halyard Australia Pty Ltd - Mask, surgical, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	O&M Halyard Australia Pty Ltd	
Postal Address	Tenancy 1 Level 1 Triniti 3 39 Dehli Road, North Ryde, NSW, 2113 Australia	
ARTG Start Date	27/02/2019	
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
O&M Halyard Inc	9120 Lockwood Boulevard Mechanicsville, Virginia, 23116 United States Of America

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	29/06/2023 5:37:15 PM
GMDN	35177 Mask, surgical, single use		
Intended Purpose	A single use device made from non woven fabrics which is placed over the nose and mouth by medical personnel to prevent the transmission of air borne organisms while surgery is being performed.		

Specific Conditions

No Specific Conditions included on Record

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