

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: Medical Industries Australia Hold Co Pty Ltd - Mask, surgical, single use 332292

ARTG entry for Medical Device Included Class 1

Medical Industries Australia Hold Co Pty Ltd Sponsor Postal Address 2 Imperata Close, Kemps Creek, NSW, 2178

24/03/2020 ARTG Start Date

Product Category Medical Device Class 1

Status Active

Medical Devices Approval Area

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**

Xiantao Tongda Non-Woven Products Co Ltd

18 Pengchang Road Xiantao, , 433018

China

Products

1. Mask, surgical, single use

Product Type Effective Date 24/03/2020 Single Device Product

GMDN 35177 Mask, surgical, single use

Intended Purpose This is a disposable device that is intended to be used to place over the nose and mouth by medical/dental personnel to prevent the

transmission of airborne organisms while surgery is being performed and also to prevent cross contamination .

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.