



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340681	Tradies Workwear and Safety - Mask, surgical, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Tradies Workwear and Safety	
Postal Address	910 South Road, Edwardstown, SA, 5039 Australia	
ARTG Start Date	31/07/2020	
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
Wenzhou Bowin Packaging Co Ltd	No 952-992 XingRong Road Wanquan Town Pingyang County Wenzhou City, Zhejiang Province, China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	31/07/2020
GMDN	35177 Mask, surgical, single use		
Intended Purpose	A disposable device worn over the nose and mouth to prevent the transmission of airborne particles. Certified to comply with standard EN149:2001+A1:2009		

Specific Conditions

No Specific Conditions included on Record

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