



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	391674	Wiselink Group Pty Ltd - Mask, surgical, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Wiselink Group Pty Ltd	
Postal Address	Suite 31 427-441 Victoria Avenue, Chatswood, NSW, 2067 Australia	
ARTG Start Date	1/07/2022	
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
Rizhao Sanqi Medical & Health Articles Co Ltd	Heshan International Industrial Park Donggang District Rizhao City, Shandong Province, 276800 China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	1/07/2022
GMDN	35177 Mask, surgical, single use		
Intended Purpose	A disposable mask used by healthcare professionals that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. The surgical mask blocks large-particle droplets, splashes, sprays, or splatter that may contain germs (viruses and bacteria), keeping it from reaching the wearer's mouth and nose. Surgical masks also reduce transmitting the wearer's saliva and respiratory secretions to others.		

Specific Conditions

No Specific Conditions included on Record

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