



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340970	Werko Australia - Mask, surgical, single use
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ARTG entry for	Medical Device Included Class 1
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Sponsor	Werko Australia
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Postal Address	2/140 Hotham Street, Balaclava, VIC, 3183 Australia
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ARTG Start Date	6/08/2020
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Product Category	Medical Device Class 1
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Status	Active
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Approval Area	Medical Devices
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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
Jiangyin Jinmao Aluminum Composite Panel Co Ltd	NO 939 QINFENG ROAD HUASHI TOWN JIANGYIN CITY, JIANGSU PROVINCE, China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	6/08/2020
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GMDN	35177 Mask, surgical, single use
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Intended Purpose	A non-sterile mask placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms.
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Specific Conditions

No Specific Conditions included on Record

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