



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	332818	Purist Australian - Mask, surgical, single use
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ARTG entry for	Medical Device Included Class 1
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Sponsor	Purist Australian
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Postal Address	PO Box 439, Camperdown, NSW, 2050 Australia
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ARTG Start Date	30/03/2020
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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
Nantong Gather Excellence-Cleaning Medical Materials Co Ltd	Kaiyuan Road No 100-1 Tian Zhuang Industrial Park Haian County, Nantong, 226600 China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	30/03/2020
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GMDN	35177 Mask, surgical, single use
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Intended Purpose	to be 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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