



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

KCM Hygiene Pty Ltd

for approval to supply

KCM Hygiene Pty Ltd - Mask, surgical, single use

ARTG Identifier	334033
ARTG Start Date	11/04/2020
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	Bergamot B0501 3 PLY face mask (Earloop) designed for medical procedures to reduce transmission of fluid and particulate matter between operator and patient, microorganisms and infectious diseases.

Manufacturer Details	Address	Certificate number(s)
Xiantao Tsw Protective Products Co Ltd	Xinming Road Pengchang Xiantao City , Hubei Province , 433018 China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Mask, surgical, single use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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