



Medical Device Details

Sponsor: Amtech Medical Ltd
P O Box 2050
Wanganui 4543
NEW ZEALAND

WAND Reference: 200514-WAND-6UOEA8

Sponsors Own Reference: G973

GMDN: Surgical face mask, single-use [35177]

Class: I

Intended Purpose: Respiratory protective device

Manufacturer: Dongguan Qiutian Plastics Co Ltd No 240 Zhongxin Middle Road
Gaobu Town
Dongguan
Guangdong Province
China

ARTG ID:

- > The device is supplied unsterilised.
- > The device is not intended to be invasive.
- > The device is intended for single use.
- > The device is not an active device.
- > The device does not contain material or ingredients of microbial origin.
- > The device does not contain material or ingredients of recombinant origin.
- > The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- > The device does not contain material or ingredients of human origin.
- > The device does not contain human blood or its components.
- > The device consists of: Single product
- > The device does not contain material or ingredients of animal origin.
- > The device is not medicated.
- > The device is not formulated.
- > The product does not contain a medicine that has consent for marketing in New Zealand.
- > The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

Status: Active