



Medical Device Details

Sponsor: Oraltec (NZ) Ltd
P O Box 33 087
Takapuna
AUCKLAND 0740
NEW ZEALAND

WAND Reference: 200617-WAND-6UVOVP

Sponsors Own Reference: Oramask Face Masks

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

Class: I

Intended Purpose: A device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed. This device is disposable.

Manufacturer: PriMed Medical Products Inc 301-1259, 91 Street SW
Edmonton
Alberta T6X 1E9
Canada

ARTG ID:

- > The device is supplied unsterilised.
- > The device is not intended to be invasive.
- > The device is not 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