



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

**Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Mask, surgical,
single use**

ARTG Identifier 297583
ARTG Start date 15/12/2017
Product Category Medical Device Included Class 1
GMDN 35177
GMDN Term Mask, surgical, single use
Intended Purpose

The device is a single use, disposable N95 face mask with a hydrophilic plastic coating on the outer layer, and a second inner layer treated with metal ions. The outer layer absorbs pathogen aerosol droplets into the inner antiviral layer where pathogens are inactivated. It helps to reduce risk of exposure to body fluids, particulate matter and both viruses and bacteria.

Manufacturer Details	Address	Certificate number(s)
Innonix Technologies Limited	13/F LiFung Centre 2 On Ping Street Siu Lek Yuen, Shatin, Hong Kong - SAR of 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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