



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Cxxxxxxxxxxx PTY LTD

for approval to supply

Cxxxxxxxxxxx PTY LTD - Public respirator, single-use

ARTG Identifier 340300
ARTG Start Date 28/07/2020
Product Category Medical Device Included Class 1
GMDN 57793
GMDN Term Public respirator, single-use
Intended Purpose KN95 protective mask certified in line with EU Standard EN 149:2001, a non sterile filtering half mask designed to be placed over the nose and mouth to protect from particulates. This respirator may also help reduce breathing in some pathogenic biological airborne particulates, but does not eliminate the risk of infection or disease. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)

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. Public respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

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