



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Pro Medidevice

for approval to supply

Pro Medidevice - N/A - Public respirator, single-use

ARTG Identifier	341395
ARTG Start Date	12/08/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public respirator, single-use
Intended Purpose	<p>Royax high quality and high-performance respirators which designed and manufactured in accordance with to the EN 149:2001+A1:2009 standard + RfU02.075 Ver 1 of the notified Bodies VG2 against COVID-19 work using the electrostatics to attract and then to trap the tiniest of existing particles.</p> <p>Our respirator is designed to protect against living organisms such as viruses, bacteria, fungi and also fine dust, fibers, aqueous mists, oil-based mists. Microorganisms (viruses, bacteria, fungi) can be transmitted by various routes.</p> <p>Respiratory protection is needed to prevent infection with organisms that are usually entered the body through inhalation (droplet/airborne). The respirator should be used together with other PPE for the health care professionals.</p> <p>The respirator is recommended for the Health Care Provider (HCP) in contact with a confirmed or suspected case of COVID-19. Also, respiratory protection is crucial to reduce the risk of airborne infections spreading when the people cough, sneeze or speak. Our product (respirator) are fitting to the face are meant to make a seal. Adjustable nose clip to prevent leakage and provide comfort.</p> <p>The respirator must be put on and removed in an order that minimizes the potential for cross contamination. Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and may result in sickness or death.</p> <p>The respirators consist of a 4-layers` construction (please refer to the 1.1. Article of this IFU), comprising two layers of high-quality spun bond material with smooth surface finish which covers two layers of outstanding performance melt blown filter material that is electrostatically charged. The electrostatic element attracts and then traps the tiniest of particulate whilst remaining easy to breathe through. The non-valve construction ensures</p>

that the wearer does not exhale potentially harmful organisms to others nearby. To be fully effective, the respirator must be put on and removed in a routine that minimizes the potential for cross contamination. The product is skin-friendly and allergy-free.

Manufacturer Details	Address	Certificate number(s)
ROYAX sro	Obchodni 107 - 251 , Cestlice , Czech Republic	

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. N/A - Public respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 341395
ARTG Start Date: 12/08/2020