



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Wiselink Group Pty Ltd

for approval to supply

Wiselink Group Pty Ltd - Surgical/medical respirator, single-use

ARTG Identifier	389571
ARTG Start Date	3/06/2022
Product Category	Medical Device Included Class 1
GMDN	57794
GMDN Term	Surgical/medical respirator, single-use
Intended Purpose	This filtering half-mask is a respiratory protection equipment and is suitable for filtrating contaminants in aerosols and provides fluid penetration resistance.

Manufacturer Details	Address	Certificate number(s)
Rizhao Sanqi Medical & Health Articles Co Ltd	Heshan International Industrial Park Donggang District Rizhao City , Shandong Province , 276800 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. Surgical/medical respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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