



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 - Gown, operating room, single use

ARTG Identifier	383370
ARTG Start Date	2/02/2022
Product Category	Medical Device Included Class 1
GMDN	35091
GMDN Term	Gown, operating room, single use
Intended Purpose	A disposable operating room gown is used during surgical procedures to protect both the patient and operating room personnel from the transfer of micro-organisms, body fluids and particulate material. Depending on product model, the gown may be fluid resistant or impervious to fluid.

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. Gown, operating room, single use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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