

# **Department of Health**

Therapeutic Goods Administration

# **Australian Register of Therapeutic Goods Certificate**

Issued to

# CoShield

for approval to supply

# CoShield - Gown, isolation, single use

ARTG Identifier 384643

ARTG Start Date 24/02/2022

Product Category Medical Device Included Class 1

**GMDN** 35492

**GMDN Term** Gown, isolation, single use

Intended Purpose A garment made of natural and/or synthetic materials intended to be

worn by healthcare providers or visitors to isolate themselves from patients. The isolation gown helps to protect the patient (e.g., burn patients) from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. This is a

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single-use garment.

Manufacturer Details	Address	Certificate number(s)
Hefei YuChen Plastic Products Co Ltd	Xianghe South Road Feidong County Hefei City , Anhui Province , 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, isolation, single use

## **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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