



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Product Category	Medical Device Included Class 1
GMDN	35492
GMDN Term	Gown, isolation, single use
Intended Purpose	A multipurpose garment, made of natural, synthetic or a combination of materials, worn by healthcare providers or visitors to isolate them from the patient. The isolation gown protects the patient, e.g. burn patients, from the transfer of infectious agents carried by the healthcare provider or visitor; or it can protect the healthcare provider or visitor from a contagious agent which has infected the patient. This is a disposable garment.

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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