



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 334480 Clets Linen & Co Pty Ltd - Gown, isolation, single use

<b>ARTG entry for</b>	Medical Device Included Class 1
<b>Sponsor</b>	Clets Linen & Co Pty Ltd
<b>Postal Address</b>	PO Box 345, Heidelberg, VIC, 3084 Australia
<b>ARTG Start Date</b>	17/04/2020
<b>Product category</b>	Medical Device Class 1
<b>Status</b>	Active
<b>Approval area</b>	Medical Devices

### 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.

### Manufacturers

#### Name

Clets Linen & Co Pty Ltd

#### Address

58 Korong Road  
Heidelberg West, VIC, 3081  
Australia

### Products

#### 1. Gown, isolation, single use

<b>Product Type</b>	Single Device Product	<b>Effective date</b>	17/04/2020
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**GMDN** 35492 Gown, isolation, single use

**Intended purpose** A multipurpose garment made of natural synthetic of a combination of materials, worn by healthcare providers or visitors to isolate them from the patient. The isolation protects the patient, eg burns patients as well as those affected by viral infections from the transfer of infectious agents carried by the healthcare provider or visitor or can protect the healthcare provider or visitor from a contagious agent, which has infected the patient. This is a disposable garment

### Specific Conditions

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