



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 334578 Ktena Knitting Pty Ltd - Gown, operating room, reusable

ARTG entry for	Medical Device Included Class 1
Sponsor	Ktena Knitting Pty Ltd
Postal Address	20 Burlington Street, Oakleigh, VIC, 3166 Australia
ARTG Start Date	18/04/2020
Product category	Medical Device Class 1
Status	Active
Approval area	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

Ktena Knitting Pty Ltd

Address

20 Burlington Street
Oakleigh, VIC, 3166
Australia

Products

1. Gown, operating room, reusable

Product Type	Single Device Product	Effective date	18/04/2020
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GMDN 11902 Gown, operating room, reusable

Intended purpose to protect both the patient and operating room personnel from the transfer of micro-organisms, body fluids and particulate material

Specific Conditions

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