



Australian Government
Department of Health
Therapeutic Goods Administration

Record Summary	372250 SHALABY MOHAMED - Gown, operating room, single use
Sponsor	SHALABY MOHAMED
Therapeutic Type	Medical Device
Product Category	Included Class Is
ARTG Start Date	5/08/2021
Postal Address	38 Narellan Street, Arana Hills, QLD, 4054 Australia
Billing Address	38 Narellan Street, Arana Hills, QLD, 4054 Australia
Product Type	Medical Device - Class Is - Included
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	Address	Certificate number(s)
Ghatwary Medical GMS	Plot 8 Block 28 2nd Industrial Zone-Borg El-Arab El-Gedida , Alexandria , Egypt	DV-2021-MC-14714-1

Products

1 . Gown, operating room, single use

Product Type	Single Device Product	Status	Current
		Effective Date	5/08/2021

GMDN 35091 Gown, operating room, single use
Functional Description Not included on record
Intended Purpose A disposable personal protective garment used in health care settings, it is designed to be worn by surgeons, physicians or the patient to protect them from the transfer of microorganisms, body fluids and particulate matters. It is also used to protect the wearer from the spread of infection or illness if the wearer comes in contact with potentially infectious liquid and solid materials. This is a single-use device and suitable for isolation also.

Variant Information

Device Information

10 Single-use devices

Specific Conditions

No Specific Conditions included on Record

Record Summary