

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Medisa Pty Ltd

for approval to supply

Medisa Pty Ltd - Mask, surgical, single use

ARTG Identifier 339840

ARTG Start Date 20/07/2020

Product Category Medical Device Included Class 1

GMDN 35177

GMDN Term Mask, surgical, single use

Intended Purpose A single use mask which is placed over the nose & mouth to prevent the

transmission of airborne micro-organisms, fluid, materials during

treatment/surgery.

Manufacturer Details	Address	Certificate number(s)
Sai Gon Medi - Life Manufacturing, Trading Medical Equipment Co Ltd	78 Street No5A Binh Hung Hoa A Ward Binh Tan District , Ho Chi Minh City , Vietnam	

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. Mask, surgical, single use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia

Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 339840 ARTG Start Date: 20/07/2020