

Australian Government

Department of Health Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Icon International Pty Ltd t/a Icon Medipharm

for approval to supply

Icon International Pty Ltd t/a Icon Medipharm - Mask, surgical, single use

ARTG Identifier	336638
ARTG Start Date	19/05/2020
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	This mask is used by medical personnel. The masks contains 4 layers, including inner layer (spunbonded layer), middle layer is melt-blown fabric (hot-sealed cotton can be added), outer layer (spunbonded layer), mask belt and nose clip. Masks are worn on the faces of people in contact with viral materials in medical facilities, to prevent virus transmission from a patient to medical staff.

Manufacturer Details	Address	ficate number(s)
Yangzhou Medline Industry Co Ltd	No 108 Jinshan Road Economic Development Zone , Yangzhou, China	

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: 336638 ARTG Start Date: 19/05/2020