



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Intex International Group Pty Ltd

for approval to supply

Intex International Group Pty Ltd - Mask, surgical, single use

ARTG Identifier	339478
ARTG Start Date	14/07/2020
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	Intended to provide protection for the user from various air borne substances including droplets. The mask also protects people around the user from exhaled droplets etc. This mask is intended for use in clinical and isolation environments.

Manufacturer Details	Address	Certificate number(s)
Henan Tuoren Medical Device Co., Ltd.	Weiyuan Industrial Zone Menggang Changyuan County , Henan , 453400 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
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