



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	339728	Intex International Group Pty Ltd - Surgical/medical respirator, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Intex International Group Pty Ltd	
Postal Address	10/2 Slough Avenue Slough Business Park, Silverwater, NSW, 2128 Australia	
ARTG Start Date	17/07/2020	
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	Address
Zhejiang Gonfor Soft-Packaging Co Ltd	No 95-99 Fanrong Road Lupu Longgang Town Cangnan County Wenzhou City, Zhejiang Province, 325802 China

Products

1 . Surgical/medical respirator, single-use			
Product Type	Single Device Product	Effective Date	17/07/2020
GMDN	57794 Surgical/medical respirator, single-use		
Intended Purpose	A non-sterile mask intended to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the worker and patients from the transfer of microorganisms, blood, body fluids, and airborne particulate materials during medical, surgical, dental, and isolation procedures. This is a single-use device. Standard EN 149:2001+A1:2009		

Specific Conditions

No Specific Conditions included on Record

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