



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 338432 Synertechcare Australia Pty Ltd - Mask, surgical, single use

ARTG entry for Medical Device Included Class 1

Sponsor Synertechcare Australia Pty Ltd

Postal Address PO Box 345, Hurstville BC, NSW, 1481
Australia

ARTG Start Date 26/06/2020

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
Synertech International Limited	Rm 9 13/F Laurels Industrial Centre 32 Tai Yau St San Po Kong, Kowloon, Hong Kong - SAR of China

Products

1 . Mask, surgical, single use

Product Type Single Device Product **Effective Date** 26/06/2020

GMDN 35177 Mask, surgical, single use

Intended Purpose Level 3 surgical masks, intended to protect healthcare personnel / patients from micro-organisms, body fluids and particulate material while medical examination and procedures are being performed.

Specific Conditions

No Specific Conditions included on Record

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Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342339	Synertechcare Australia Pty Ltd - Surgical/medical respirator, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Synertechcare Australia Pty Ltd	
Postal Address	PO Box 345, Hurstville BC, NSW, 1481 Australia	
ARTG Start Date	26/08/2020	
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.
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Manufacturers

Name	Address
Synertech International Limited	Rm 9 13/F Laurels Industrial Centre 32 Tai Yau St San Po Kong, Kowloon, Hong Kong - SAR of China

Products

1 . Surgical/medical respirator, single-use			
Product Type	Single Device Product	Effective Date	26/08/2020
GMDN	57794 Surgical/medical respirator, single-use		
Intended Purpose	A non-sterile filtering mask [N95 (filter efficiency 95%)] designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the wearer and patient from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., influenza pandemic). It is made of multiple layers of non-woven polymers to produce a soft and flexible. It is secured using elastic head straps; it may incorporate a forming nosepiece (metal wire). This is a single-use device.		

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Therapeutic Goods Administration

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Summary for ARTG Entry:	350650	Synertechcare Australia Pty Ltd - Mask, surgical, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Synertechcare Australia Pty Ltd	
Postal Address	PO Box 345, Hurstville BC, NSW, 1481 Australia	
ARTG Start Date	3/12/2020	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

Conditions

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- 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
Synertech International Limited	Rm 9 13/F Laurels Industrial Centre 32 Tai Yau St San Po Kong, Kowloon, Hong Kong - SAR of China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	3/12/2020
GMDN	35177 Mask, surgical, single use		
Intended Purpose	Level 2 disposable face mask intended to protect healthcare personnel / patients from micro-organisms, body fluids and particulate material while medical examination and procedures are being performed.		

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Summary for ARTG Entry:	342339	Synertechcare Australia Pty Ltd - Surgical/medical respirator, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Synertechcare Australia Pty Ltd	
Postal Address	PO Box 345, Hurstville BC, NSW, 1481 Australia	
ARTG Start Date	26/08/2020	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

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Manufacturers

Name	Address
Synertech International Limited	Rm 9 13/F Laurels Industrial Centre 32 Tai Yau St San Po Kong, Kowloon, Hong Kong - SAR of China

Products

1 . Surgical/medical respirator, single-use			
Product Type	Single Device Product	Effective Date	26/08/2020
GMDN	57794 Surgical/medical respirator, single-use		
Intended Purpose	A non-sterile filtering mask [N95 (filter efficiency 95%)] designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the wearer and patient from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., influenza pandemic). It is made of multiple layers of non-woven polymers to produce a soft and flexible. It is secured using elastic head straps; it may incorporate a forming nosepiece (metal wire). This is a single-use device.		

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Summary for ARTG Entry: 350650 Synertechcare Australia Pty Ltd - Mask, surgical, single use

ARTG entry for Medical Device Included Class 1

Sponsor Synertechcare Australia Pty Ltd

Postal Address PO Box 345, Hurstville BC, NSW, 1481
Australia

ARTG Start Date 3/12/2020

Product Category Medical Device Class 1

Status Active

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Manufacturers

Name	Address
Synertech International Limited	Rm 9 13/F Laurels Industrial Centre 32 Tai Yau St San Po Kong, Kowloon, Hong Kong - SAR of China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	3/12/2020
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GMDN 35177 Mask, surgical, single use

Intended Purpose Level 2 disposable face mask intended to protect healthcare personnel / patients from micro-organisms, body fluids and particulate material while medical examination and procedures are being performed.

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ARTG entry for	Medical Device Included Class 1	
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Product Type	Single Device Product	Effective Date	26/08/2020
GMDN	57794 Surgical/medical respirator, single-use		
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Products

1 . Mask, surgical, single use

Product Type	Single Device Product	Effective Date	3/12/2020
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GMDN 35177 Mask, surgical, single use

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