

Australian Standard™

**Single-use face masks for use in  
health care**

This Australian Standard was prepared by Committee HE-013, Surgical Apparel. It was approved on behalf of the Council of Standards Australia on 19 November 2002 and published on 31 December 2002.

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The following are represented on Committee HE-013:

- Australian Chamber of Commerce and Industry
- Australian College of Operating Room Nurses
- Australian Dental Association
- Australian Dental Industry Association
- Australian Industry Group
- Australian Nursing Federation
- Australian Private Hospitals Association
- Commonwealth Department of Health and Ageing
- Department of Defence
- Department of Human Services, Vic.
- Federation of Sterilizing Research and Advisory Councils of Australia
- Medical Industry Association of Australia
- N.S.W. Health Department
- Royal Australasian College of Surgeons
- Testing Interests

Additional interests participating in the preparation of this Standard:

- Medical manufacturing interests

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Australian Standard™

**Single-use face masks for use in  
health care**

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## PREFACE

This Standard was prepared by the Standards Australia Committee HE-013, Surgical Apparel, to supersede AS 4381—1996, *Surgical face masks*.

The objective of this revision is to introduce three different levels of mask protection depending on its use, to minimize the risk of possible biological cross-contamination.

Single use face masks for use in health care have a limited application and are designed for use in procedures that do not require the degree of respiratory protection usually provided by respiratory protective devices. It is, therefore, incumbent on users to ensure that appropriate face masks are worn for their intended purpose.

AS/NZS 1715, *Selection, use and maintenance of respiratory protective devices*, provides advice on the selection of respirators intended to prevent the inhalation of contaminated air in a variety of conditions which are beyond the scope of this Standard.

This edition differs from the 1996 Standard in the following principal areas:

- (a) There are three types of masks, depending on their application.
- (b) There is a new test for fluid resistance of fluid resistant face masks.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the appendix to which they apply. A ‘normative’ appendix is an integral part of a Standard, whereas an ‘informative’ one is for information or guidance only.

In the preparation of this Standard, cognisance has been taken of ASTM F2100-02, *Standard test method for performance of materials used in medical face masks*.

## CONTENTS

	<i>Page</i>
1 SCOPE .....	4
2 REFERENCED DOCUMENTS .....	4
3 DEFINITIONS .....	4
4 DESIGN .....	6
5 MATERIALS .....	6
6 CONSTRUCTION .....	6
7 PHYSICAL REQUIREMENTS .....	7
8 PACKAGING OF MASKS .....	8
9 MARKING .....	8

## APPENDICES

A MEANS OF DEMONSTRATING COMPLIANCE WITH THIS STANDARD .....	9
B METHOD FOR DETERMINING BACTERIAL FILTRATION EFFICIENCY .....	11
C METHOD FOR DETERMINING PARTICLE FILTRATION EFFICIENCY .....	15
D METHOD FOR DETERMINING DIFFERENTIAL PRESSURE (BREATHABILITY) .....	17
E METHOD FOR DETERMINING FLUID RESISTANCE OF FLUID RESISTANT FACE MASKS.....	20
F METHOD FOR DETERMINING STRENGTH OF TIES AND TIE ATTACHMENT .....	28

## STANDARDS AUSTRALIA

### Australian Standard Single-use face masks for use in health care

#### 1 SCOPE

This Standard sets out requirements for single-use face masks which are used in health care where it is necessary to keep cross-contamination between the health care worker and the patient to a minimum. The masks are intended for use in the operating room, and for medical and dental procedures and applications.

The Standard does not apply to situations where an additional degree of respiratory protection may be required from the risk of airborne transmission infection, e.g. TB and surgical plume.

NOTE: Alternative means of determining compliance with this Standard are given in Appendix A.

#### 2 REFERENCED DOCUMENTS

The documents below are referred to in this Standard.

##### AS

- |      |  |
|------|--|
| 1199 | Sampling procedures and tables for inspection by attributes                  |
| 1399 | Guide to AS 1199—Sampling procedures and tables for inspection by attributes |

##### AS/NZS ISO

- |          |   |
|----------|---|
| 9001     | Quality management systems—Requirements   |
| 9004     | Quality management systems—Guidelines for performance improvements                  |
| HB 18    | Guidelines for third-party certification and accreditation                          |
| HB 18.28 | Guide 28—General rules for a modified third-party certification system for products |

##### ASTM

- |       |  |
|-------|--|
| D1331 | Standard test methods for surface and interfacial tension of solutions of surface-active agents. |
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#### 3 DEFINITIONS

For the purpose of this Standard the definitions below apply.

##### 3.1 Bacterial filtration efficiency (BFE)

The efficiency of the mask as a barrier to the passage of aerosolized bacteria.

##### 3.2 Differential pressure ( $\Delta P$ ) (breathability)

Air permeability of the mask, measured by determining the pressure differential across the mask.

##### 3.3 Facial fit

Ability of the mask to adequately cover the nose and mouth area of the wearer, so as to prevent the inhalation and exhalation of deleterious matter.