AS 4381:2015

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Australian STANDARD

Single-use face masks for use in health care

STANDARDS Australia

This Australian Standard® was prepared by Committee HE-013, Surgical Apparel. It was approved on behalf of the Council of Standards Australia on 11 November 2015.
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- Australasian College for Infection Prevention and Control
- Australian Chamber of Commerce and Industry
- Australian College of Operating Room Nurses
- Australian Dental Association
- Australian Nursing and Midwifery Federation
- Medical Technology Association of Australia
- NSW Health
- Queensland Health
- Royal College of Pathologists of Australasia
- Testing Interests, Australia
- Therapeutic Goods Administration

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Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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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—2002, *Single-use face masks for use in health care*.

The objective of this revision is to update and harmonize the testing of single-use surgical masks with relevant American Standards (ASTM) and European Norms (EN) as well as to provide a new classification system for the selection of a single-use face mask with a suitable barrier rating for various applications in health care.

Single-use face masks have specific, limited applications and are designed for use in procedures that do not require respiratory protection from the airborne transmission pathway. It is therefore incumbent on users to ensure that appropriate face masks are worn only for their intended purpose, i.e. to provide barrier protection to minimize mucous membrane exposure to infectious microbial droplets.

AS/NZS 1715, *Selection, use and maintenance of respiratory protective equipment* provides advice on the selection of respirators for use when respiratory protection from airborne hazards is required.

This edition differs from the 2002 Standard in the following principal areas:

(a) There are three defined barrier level ratings for single-use masks each for use in certain defined procedures.

(b) All testing required for the masks has been aligned with the equivalent ASTM and/or EN test methods. The Particle Filtration Efficiency (PFE) test is no longer required—this created some confusion regarding the type of protection provided and did not improve the relevant performance characteristics of the mask for use in health care.

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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 surgical, medical and dental procedures. They form part of the personal protective equipment (PPE) used to minimize mucous membrane exposure to infectious microbial droplets.

NOTE: For respiratory protection from airborne infectious agents, e.g. tuberculosis (TB) and surgical plume, refer to AS/NZS 1715.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS/NZS
1715 Selection, use and maintenance of respiratory protective equipment

AS ISO
13485 Medical devices—Quality management systems—Requirements for regulatory purposes

ISO
22609 Clothing for protection against infectious agents—Medical face masks—Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

ASTM
F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

F1862/F1862M-13 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

EN
14683 Medical face masks—Requirements and test methods

3 DEFINITIONS

For the purpose of this Standard, the following definitions apply.

3.1 Bacterial filtration efficiency

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

3.2 Differential pressure (ΔP) (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.