

AS 4381: 2015

UNDERSTANDING THE NEW AUSTRALIAN MASK STANDARDS

In December 2015, Standards Australia published an updated version of the standard for 'Single-use face masks for use in health care'. The objective was to simplify the standard and harmonise with the North American ASTM F2100-11 and European (EN) 14683.

OLD STANDARD (AS) 4381:2002:

(AS) 4381: 2002 SINGLE USE FACE MASKS				
CHARACTERISTICS	GENERAL PURPOSE	SUBMICRON	FLUID RESISTANT	TEST METHOD
	For general purpose medical procedures, where the wearer is not at risk of blood or bodily fluid splash	For tasks where the health care worker is not at risk of blood or bodily fluid splash, and requires a mask with submicron filter efficiencies	For all surgical procedures, or in any area where the health care worker is at risk of blood or bodily fluid splash, and requires a fluid resistant mask with submicron filter efficiencies	
Bacterial Filtration Efficiency (BFE) % (3 µm)	95% (min)	98% (min)	98% (min)	AS4381
Particulate Filtration Efficiency (PFE) % (0.1 µm)	Not Required	98% (min)	98% (min)	AS4381
Differential Pressure (Delta P) mm H ₂ O	5.0 (max)	5.0 (max)	5.0 (max)	AS4381
Resistance to penetration by synthetic blood (fluid resistance) at 16.0 kPa pressure	Not Required	Not Required	No evidence of blood reaching the inner layer of material	AS4381

NEW STANDARD (AS) 4381:2015: RED INDICATES CHANGE

(AS) 4381: 2015 SINGLE USE FACE MASKS				
CHARACTERISTICS	LEVEL 1	LEVEL 2	LEVEL 3	TEST METHOD
	Level 1 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the minimum velocity specified in Table 2, bacterial filtration efficiency and differential pressure. APPLICATIONS: For general purpose medical procedures, where the wearer is not at risk of blood or bodily fluid splash or to protect staff and/or the patient from droplet exposure to microorganisms (e.g. patient with upper respiratory tract infection visits GP)	Level 2 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the middle velocity specified in Table 2, bacterial filtration efficiency and differential pressure. APPLICATIONS: For use in emergency departments, dentistry, changing dressings on small or healing wounds where minimal blood droplet exposure may possibly occur (e.g. endoscopy procedures)	Level 3 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the maximum velocity specified in Table 2, bacterial filtration efficiency and differential pressure. APPLICATIONS: For all surgical procedures, major trauma first aid or in any area where the health care worker is at risk of blood or bodily fluid splash (e.g. orthopaedic, cardiovascular procedures)	
Bacterial Filtration Efficiency (BFE) %	≥ 95%	≥ 98%	≥ 98%	ASTM F2101-14 or EN 14683:2014
Particulate Filtration Efficiency (PFE) % (0.1 µm)	Not Required	Not Required	Not Required	N/A
Differential Pressure (Delta P) mm H ₂ O/cm ²	< 4.0	< 5.0	< 5.0	EN 14683:2014
Resistance to penetration by synthetic blood (fluid resistance) min pressure in mm Hg for pass result	80mm Hg	120mm Hg	160mm Hg	ASTM F1862 / F1862M-13 or ISO 22609
PLUS: Requires Instructions For Use, "The masks should be packed such that each mask can be removed without becoming entangled in another"				

A COMPARISON OF STANDARDS:

AUSTRALIA: AS 4381 (2002 vs 2015), US: ASTM F2100-11, EUROPE: EN 14683-14

CLASSIFICATION			
AS 4381-2015 NEW	Level 1	Level 2	Level 3
AS 4381-2002 OLD	General Purpose	Submicron	Fluid Resistant
US: ASTM F2100-11	Level 1	Level 2	Level 3
EUROPE: EN 14683-14	Type 1a	Type II	Type IIR
BACTERIAL FILTRATION EFFICIENCY (BFE) %			
AS 4381-2015 NEW	≥ 95	≥ 98	≥ 98
AS 4381-2002 OLD	≥ 95	≥ 98	≥ 98
US: ASTM F2100-11	≥ 95	≥ 98	≥ 98
EUROPE: EN 14683-14	≥ 95	≥ 98	≥ 98
DIFFERENTIAL PRESSURE (Delta P) mm H ₂ O/CM ²			
AS 4381-2015 NEW	< 4	< 5	< 5
AS 4381-2002 OLD	≤ 5	≤ 5	≤ 5
US: ASTM F2100-11	< 4	< 5	< 5
EUROPE: EN 14683-14	< 3	< 3	< 5
PARTICLE FILTRATION EFFICIENCY (PFE) % (0.1µm)			
AS 4381-2015 NEW	–	–	–
AS 4381-2002 OLD	–	≥ 98	≥ 98
US: ASTM F2100-11	≤ 95	≥ 98	≥ 98
EUROPE: EN 14683-14	–	–	–
FLUID RESISTANCE (mm Hg)			
AS 4381-2015 NEW	≥ 80	≥ 120	≥ 160
AS 4381-2002 OLD	–	–	120
US: ASTM F2100-11	≥ 80	≥ 120	≥ 160
EUROPE: EN 14683-14	–	–	≥ 160
FLAME SPREAD			
AS 4381-2015 NEW	–	–	–
AS 4381-2002 OLD	–	–	–
US: ASTM F2100-11	Class 1	Class 1	Class 1
EUROPE: EN 14683-14	–	–	–
BIOBURDEN (cfu/g)			
AS 4381-2015 NEW	–	–	–
AS 4381-2002 OLD	–	–	–
US: ASTM F2100-11	–	–	–
EUROPE: EN 14683-14	≤ 30	≤ 30	≤ 30



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