

## *Document Detail*

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## *Review*

**Owner Role**

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Table 1 below summarizes the performance requirements met for the Com-Fit product line of face masks.

<b>Table 1 Com-Fit Mask Classifications, ASTM F2100 and EN 14683</b>			
<b>P/N</b>	<b>Product Description</b>	<b>ASTM F2100 Level</b>	<b>EN 14683 Type</b>
20324	Com-Fit Fluid Resistant Procedural Blue Face Mask with Soft Earloop	-	IIR
20325	Com-Fit Fluid Resistant Procedural Pink Face Mask with Soft Earloop	-	IIR
20326	Com-Fit Super High Filtration Face Mask with Soft Earloop	1	II
20328	Com-Fit Super High Filtration Face Mask with Soft Earloop and Eye Shield	1	II
20336	Com-Fit Super High Filtration Tie-On Face Mask	1	II
20340	Com-Fit Easy Breathe Face Mask, Soft Earloop	-	II
20342	Com-Fit Easy Breathe Face Mask, Tie-On	-	II
20344	Com-Fit Super Sensitive Tie-On Face Mask	1	II
20346	Com-Fit Super Sensitive Face Mask with Soft Earloop	1	II
20350	Com-Fit Groovy Face Mask with Soft Earloop	-	IIR
20352	Com-Fit Plush Face Mask With Soft Earloop, ASTM Level 1	1	II
20353	Com-Fit Plush Face Mask With Soft Earloop, ASTM Level 2	2	IIR
20354	Com-Fit Plush Face Mask With Soft Earloop, ASTM Level 3	3	IIR
20355	Com-Fit Plush Natural Fit Face Mask with Soft Earloop, ASTM 1	1	II
20356	Com-Fit Plush Natural Fit Face Mask with Soft Earloop, ASTM 2	2	IIR
20357	Com-Fit Plush Natural Fit Face Mask with Soft Earloop, ASTM 3	3	IIR

Table 2 summarizes the performance requirements that must be met for each ASTM F2100 Level.

<b>Table 2: Medical Face Mask Material Requirements by Performance Level (ASTM F2100-19)</b>			
<b>Characteristic</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Bacterial filtration efficiency, %	≥ 95	≥ 98	≥ 98
Differential pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	< 5.0	< 6.0	< 6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥ 95	≥ 98	≥ 98
Resistance to penetration by synthetic blood, minimum pressure in mmHg for pass result	80	120	160
Flame Spread	Class 1	Class 1	Class 1

Table 3 summarizes the performance requirements that must be met for each EN 14683 Type.

<b>Table 3: Performance Requirements for Medical Face Masks (EN 14683:2019)</b>			
<b>Test</b>	<b>Type I<sup>a</sup></b>	<b>Type II</b>	<b>Type IIR</b>
Bacterial filtration efficiency, %	≥ 95	≥ 98	≥ 98
Differential pressure, Pa/cm <sup>2</sup>	< 40	< 40	< 60
Splash resistance pressure, kPa	Not required		≥ 16.0
Microbial Cleanliness, cfu/g	≤ 30	≤ 30	≤ 30

<sup>a</sup> Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.