

Kimberly-Clark Comments on "Draft Guidance for Industry and FDA Staff"

Replace the term surgical with the term medical as it refers to mask type. This occurs throughout the document in the following locations:

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Page 1: L3, L18, L24

Page 2: L42, L45

Page 4: L135, L136

Page 6: L187, L197

Page 7: L217, L218, L219, L223

Page 8: L248, L249, L252, L253



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OTHER CHANGES:

Page 1:

L18: replace "operating room" with "healthcare"

L18/19: remove: during surgical procedures

L19: remove surgical both the surgical patients

L19: replace "operating room" with "healthcare"

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Page 3:

L80: Add the sentence: It is recommended that you use product categories and performance levels as described in ASTM F2100.

L100: Add footnote #3 after "document".

Add footnotes #3: Reference ASTM F2100 Specification for Medical Face Masks.

Page 4:

L140: Remove "We recommend that"

L141: replace "also" with "must"

Page 5:

L160: replace complete bullet with "type of fabric: spunbond, meltblown, wetlaid, etc."

Page 6:

L180: delete "on the side for blow by prevention"

L184: delete "duck bill"; add at end "shaped, pouch, etc."

L195: in table, 3rd line add "and particle filtration efficiency (PFE) – Section 8"

Page 7:

L211: reword "... of the mask to resist the penetration"

L212: Delete "we recommend that you"

L214: Delete "00a"

L217: Delete "00a"

L226: Remove "Filter Efficiency Performance" and replace with "Particulate Filtration Efficiency"

L230: add at end of sentence "(ASTM 1215)."

L235: Remove "We recommend that you"

L235/236: Remove "fluid resistance" and replace with "BFE"

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L236: Remove “one of the test methods or standards listed below.” And replace with “ASTM F2101 as listed below.”

L238: Remove this bullet, this test method is obsolete

L241: Remove this bullet, this test method is an “in vivo” method and not reliably reproducible.

Page 8:

L251: remove “material”

L252: remove “material”

L253: remove “and comfort”, remove “We recommend”

L254: Reword sentence to read “Delta-P is demonstrated according to the following standard.”

L254: Add new sentence at end “In general a lower Delta-P translates to increased breathability.”

L259: Reword the sentence to read “When reporting Delta-P, report face velocity or sample size and flow rates – referencing the test method used.”

L261: Remove this table. Comfort and heat are not directly correlated to Delta-P and do not take into account the factors of humidity, etc. In addition, comfort is a subjective term.

L266: Remove “Flammability Test Method”, following (16 CFR 1610). The correct title should read “The Standard for the Flammability of Clothing Textiles”

L268: Remove the # sign in front of 702. Change the title to read correctly “Standard for Classification of the Flammability of Wearing Apparel.”

Page 9:

L270: Remove this bullet point; this test method was developed for surgical fabrics.

L275: Reword sentence to read “Medical masks must meet Class 1 (16 CFR 1610) flammability.

L276: Add the following sentence “Medical masks may be rated as NFPA 702-1980 Class 1, Class 2, or Class 3.

L278: Insert “(NFPA)” in front of “Class 4”

L298: Insert “(16 CFR 1610)” behind “Class 3”

L298: Remove “surgical mask materials”

L301: Remove “NFPA, or CPSC” and replace with “(CPSC)”

L305: Add bolded bullet line “For Class 4 (NFPA 702-1980) this device does not meet the NFPA flammability standard.”

Page 11:

L315: Reword the second box to read “Particulate Filtration Efficiency”, change the units to “(%)”

L315: In the Differential Pressure box, need to add the units “(mm H₂O/cm²)”

L317: Add a line/box to the table for “Differential Pressure per NIOSH method”