ASTM	Minimum Performance	Low Performance	Level 1 Minimal Protection	Level 2 Low Protection	Level 3 Moderate Protection	Level 4 High Protection
EXAMPLE ITEM	Face Shield / Face Cover		Face Mask	Surgical Mask	Surgical Mask	N95 Respirator
DESCRIPTION	Ideal as a simple physical barrier for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols. Utility Mask (Tissue/Tissue) Physical Barrier Only No LEVEL Performance Level Filtration Efficiency N/A	Ideal as a comfortable substitute for earloop face masks, this mask is a simple physical barrier for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols. Surgical Molded Utility Mask Physical Barrier Only No LEVEL Performance Level ** Filtration Efficiency N/A **Unless mask manufacturer certifies mask meets ASTM performance Level	Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection	Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection	Surgical Masks Intended to Provide Liquid Barrier Protection	N95 layers need to include: Layer 1- surface non woven fabric 25g weight- spun bound polypropylene Layer 2- melt blown filter layer 25-50g in weight- spun-bound polypropylene Layer 3- filter layer hot air cloth 25-50 g- cellulose/polyester Layer 4- surface non woven fabric 25g - spun bound polypropylene
ASTM Rating	N/A		ASTM Level 1: Low fluid resistance, ideal for procedures where low amounts of fluid, spray and/or aerosols are produced.	ASTM Level 2: Moderate fluid resistance, ideal for procedures where moderate tolight amounts of fluid, spray and/or aerosols are produced.	ASTM Level 3: High fluid resistance, ideal for procedures where heavy amounts of fluid, spray and/or aerosols are produced.	N95 Respirator
FDA REQUIREMENTS	N/A		Establishment registration required for medical use Device listing is required on FDA registration Certification is done on the material, not the product itself	Establishment registration required for medical use Device listing is required on FDA registration Certification is done on the material, not the product itself	Establishment registration required for medical use Device listing is required on FDA registration Certification is done on the product itself; looking to confirm that the materials and construction meet requirements.	Establishment registration required for medical use Device listing is required on FDA registration Produced in a sterile environment Certification is done on the product itself; looking to confirm that the materials and construction meet requirements. The filtration can be certified by material. The FDA will want to understand the manf process to ensure that additional holes are not produced, which compromise the effectiveness. FDA registration is still required for masks.
PACKAGING	N/A		Does not need individual packaging; Shipping box should be clean and lined. If not FDA approved, a disclaimer of 'not for medical use' must be displayed.	Does not need individual packaging; Shipping box should be clean and lined. If not FDA approved, a disclaimer of 'not for medical use' must be displayed.	Requires individual packaging + FDA labeling.	Requires individual packaging + FDA labeling.
MASK LABELING GUIDELINES	N/A		Country of origin Care instructions (if reusable) Fiber content Size	Country of origin Care instructions (if reusable) Fiber content Size	Country of origin Care instructions (if reusable) Fiber content Size	Country of origin Care instructions (if reusable) Fiber content Size
FDA LABELING	N/A		Labels can be per package, not per garment: Needs to have a control/brand name AAMI Level needs to be clearly stated Lot identifier needs to be on label FDA does not object to your marketing and distribution of the gown and surgical apparel products in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner: 1. The apparel is not labeled as "surgical"; rather it may be labeled as a “gown”, “toga”, “hood”, etc. 2. It states it may be used when FDA cleared gowns or apparel are unavailable 3. Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected; 4. Includes a recommendation against use in a clinical setting where the infection risk level is high; 5. It makes no claims regarding flammability; 6. It makes no claims of antimicrobial or antiviral protection; 7. It makes no claims of infection prevention or reduction; 8. Contains a list of the body contacting materials.		Labels can be per package, not per garment: Needs to have a control/brand name Lot identifier needs to be on label Material which will come in contact with the body needs to be called out by the common material name. If it's reusable, the re-sterilization + re-packaging method must be detailed on a product sheet with each mask	Labels can be per package, not per garment: Needs to have a control/brand name Lot identifier needs to be on label Material coming in contact with the body needs to be called out by the common material name. Sterilization method must be listed (i.e. heat, chemical, etc) If it's reusable, the re-sterilization + re-packaging method must be detailed on a product sheet with each mask

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Available Patterns on Gerber PPE Resource site (https://sites.google.com/gerbertechnology.com/gerbertaskforce/home)	PPE-L1-AccuMark Mask with Darts PPE-L1-AccuMark Mask with Pleats PE-L1-Cutworks Masks RB01-Mask (OPM) PPE-L1-Cutworks Face Shields PPE-L1-OpenSourceFaceShield					