ANSI / AAMI PB70 Barrier Performance	Level 1 Minimal Protection	Level 2 Low Protection	Level 3 / "Surgical Gown" Moderate Protection	Level 4 / "Surgical Isolation Gown" High Protection
EXAMPLE ITEM	Patient gown (protection gown)	Examination gown	Surgical gown	Surgical isolation gown
TYPICAL ENVIRONMENT FOR USAGE	Can be used for Standard Precautions and Contact Precautions Basic Care Standard Hospital Medical Unit	Can be used by Nurses, Standard Precautions, Contact Precautions Blood draw from a vein Suturing ICU Pathology lab	Used in the Emergency Room, the ICU, by Nurses, for Standard Precautions, Contact Precautions Arterial blood draw IV insertion Emergency room Trauma Typically pathogen resistant	Used in the Emergency Room, the ICU, by Nurses, for Standard Precautions, Contact Precautions Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods
FDA DEFINITION	Non-surgical gowns are Class I devices (exempt from premarket review) intended to protect the wearer from the transfer of microorganisms and body fluids in low or minimal risk patient isolation situations. Non-surgical gowns are not worn during surgical procedures, invasive procedures, or when there is a medium to high risk of contamination. Like surgical isolation gowns, non-surgical gowns should also cover as much of the body as is appropriate to the task. As referenced in Figure 2, all areas of the non-surgical gown except bindings, cuffs, and hems are considered critical zones of protection and must meet the highest liquid barrier protection level for which the gown is rated. All seams must have the same liquid barrier protection as the rest of the gown.		A surgical gown is regulated by the FDA as a Class II medical device that requires a 510(k) premarket notification. A surgical gown is a personal protective garment intended to be worn by health care personnel during surgical procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate matter. Because of the controlled nature of surgical procedures, critical zones of protection have been described by national standards. The critical zones include the front of the body from top of shoulders to knees and the arms from the wrist cuff to above the elbow. All surgical gowns must be labeled as a surgical gown.	Surgical isolation gowns are used when there is a medium to high risk of contamination and a need for larger critical zones than traditional surgical gowns. Surgical isolation gowns, like surgical gowns, are regulated by the FDA as a Class II medical device that requires a 510(k) premarket notification. All areas of the surgical isolation gown except bindings, cuffs, and hems are considered critical zones of protection and must meet the highest liquid barrier protection level for which the gown is rated. **All seams must have the same liquid barrier protection as the rest of the gown.** Additionally, the fabric of the surgical isolation gown should cover as much of the body as is appropriate for the intended use.
FDA REQUIREMENTS	Establishment registration required Device listing is required on FDA registration Certification is done on the material, not the product itself Good Manufacturing Practices (as defined by the FDA cGMP guidelines) confirmed to be in place	Establishment registration required Device listing is required on FDA registration Certification is done on the material, not the product itself Good Manufacturing Practices (as defined by the FDA cGMP guidelines) confirmed to be in place	Establishment registration required Device listing is required on FDA registration Certification is done on the product itself; the FDA will confirm that the materials and construction meet requirements Good Manufacturing Practices (as defined by the FDA cGMP guidelines) confirmed to be in place	Establishment registration required Device listing is required on FDA registration Certification is done on the product itself; the FDA will confirm that the materials and construction meet requirements Produced in a sterile environment
TESTING FACILITIES	Labs need the ISO 17025 certification to FDA certify materials/products, examples include: Nelson Labs Bureau Veritas SGS Labs			
TEST METHOD	Water Resistance: Impact Penetration AATCC 42	Water Resistance: Impact Penetration AATCC 42 Water Resistance: Hydrostatic Pressure AATCC 127	Water Resistance: Impact Penetration AATCC 42 Water Resistance: Hydrostatic Pressure AATCC 127	Viral Penetration: ASTM F1671
TEST DEFINITION	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	ASTM F1671 Measures the resistance of fabrics to bloodborne pathogens using viral penetration at 2psi and ambient pressure. ASTM F1671 Measures the resistance to penetration by blood borne pathogens using a surrogate microbe under conditions of continuous liquid contact.
MATERIAL REQUIREMENT	Water Impact </= 4.5g	Spray impact </= 1.0 g Hydrostatic Pressure >/= 20 cm	Spray impact </= 1.0 g Hydrostatic Pressure >/= 50 cm	Totally impervious
REUSABLE GOWNS fabric examples	Burlington Maxima, Burlington Maxima ESD, Burlington C3, Milliken Integrity 1800, Milliken Integrity 2000			Milliken Integrity 2000

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DISPOSABLE GOWNS fabric examples	Not adherent to AAMI standards but FDA Approved for use in Standard Precautions, Contact Precautions, and by Nurses SPUNBOUND POLYPROPYLENE, AND POLYETHYLENE --- AAMI Level 1-4 SMS Material DuPont Tyvek 1222A			AAMI Level 1-4 SMS Material & Coated Polypropylene
PACKAGING	Does not need individual packaging; Shipping box should be clean and lined. If not FDA approved, a disclaimer (see below) must be displayed.	Does not need individual packaging; Shipping box should be clean and lined. If not FDA approved, a disclaimer (see below) must be displayed.	Requires individual packaging + FDA labeling.	Requires individual packaging + FDA labeling.
GARMENT LABELING	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	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 AAMI Level 1 needs to be clearly stated 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.	Labels can be per package, not per garment: Needs to have a control/brand name AAMI Level 1 needs to be clearly stated 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 garment
Available Patterns on Gerber PPE Resource site (https://sites.google.com/gerbertechnology.com/gerbertaskforce/home)	PE-L1-Gown Reusable (AZFS) PE-L1-Gown Disposable (AZFS) PPE-L1-Surgical Gown Level 1 GN01-Gown (OPM) MMSC Cap (OPM)	PE-L1-Gown Reusable (AZFS) PE-L1-Gown Disposable (AZFS) PPE-L1-Surgical Gown Level 1 GN01-Gown (OPM) MMSC Cap (OPM)	PPE-L1-Surgical Gown Level 3	