Gowns

Fast Facts:

Reuseable Gowns for Medical Professionals

A quick guide for medical device manufacturers on the procurement of technical textiles for resuable PPE gowns

While there are slightly different requirements around the world when it comes to resuable gowns for PPE, essentially all gowns need to provide a barrier for the wearer to keep them safe in the workplace, whether that is in a medical or a commercial environment.

This Fast Facts sheet sets out the different standards for gown manufacture in the US, UK and Europe; and provides information about Trelleborg Engineered Coated Fabrics product range.

European & UK Gown standards

The UK follows European standards in regards to testing and conformity for resuable gowns. There is one type – a Surgical Gown. These are classified as a Class I Medical Device, which means they have the lowest risk to the patient and/or user.

Testing against European standards tends to be more rigourous, and Class I medical devices need to be registered with the MHRA if they are to be sold in the UK market.

European gowns need to demonstrate they are a barrier for bacteria.

The main requirements for Surgical Gowns are as follows:

	TEST	METHOD
EN 13795-1:2019	Pre-treatment: 5 Cycles (If Reusable)	ISO 6330
	Resistance to Microbial Penetration (Dry)	EN ISO 22612
	Resistance to Microbial Penetration (Wet)	EN ISO 22610
	Microbial Cleanliness	EN ISO 11737-1
	Particulate Matter	ISO 9073-10
	Linting	ISO 9073-10
	Resistance to Liquid Penetration	ISO 811
	Burst Strength – Dry	EN 13938-1
	Burst Strength – Wet	EN 13938-1
	Tensile Strength – Dry	EN 29073-3
	Tensile Strength – Wet	EN 29073-3

	TEST	METHOD
EN 14126:2003	Synthetic Blood Test (for screening purposes)	ISO 16603
	Bacteriophage Test (when strikethrough is expected)	ISO 16604 (1.75kPa)
	Penetration by infective agents due to mechanical contact with substances containing contaminated liquids	Annex A of standard (wet bacterial test equivalent to ISO 22610)
	Resistance to Penetration by Contaminated Liquid Aerosols	ISO 22611
	Resistance to Penetration by Contaminated Solid Particles	ISO 22612

UK CLEANING: Tested up to 75 washes – no loss of performance

US Gown standards

These are regulated by the US Food and Drug Administration (FDA), and this classifies gowns by their intended purpose:

NON-SURGICAL GOWNS

Classified as a Class I device, so no need for premarket approval.

Worn at Level 1-2, to protect the wearer in low or minimal risk patient isolation situations.

SURGICAL GOWNS

Classified as a Class II medical device by the FDA and requiring 510(k) premarket approval.

Can be worn at any Level (1-4) and must be labelled as a surgical gown.

SURGICAL ISOLATION GOWNS

Classified as a Class II medical device by the FDA and requiring 510(k) premarket approval.

Worn at Level 3-4, where there is a need for a larger critical zone than traditional surgical gowns. Level 4 gowns need to demonstrate they are a barrier for viruses.

US CLEANING: Tested up to 75 washes – no loss of performance

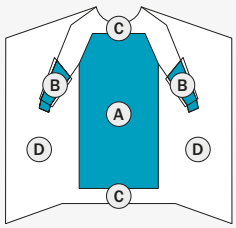
CRITICAL ZONES

CRITICAL ZONES FOR SURGICAL GOWNS

The entire front of the gown (areas A, B, and C) is required to have a barrier performance of at least level 1.

The critical zone compromises at least areas A and B.

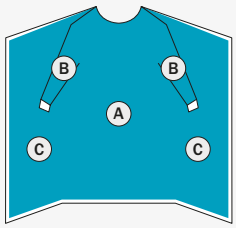
The back of the surgical gown (area D) may be nonprotective.



CRITICAL ZONES FOR SURGICAL ISOLATION GOWNS AND NON-SURGICAL GOWNS

The entire gown (areas A, B, and C), including seams but excluding cuff, hems, and bindings, is required to have a barrier performance of at least Level 1.

Surgical isolation gowns are used when there is a medium to high risk of contamination and need for larger critical zones than traditional surgical gowns.



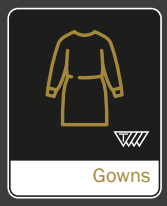
GOWN LEVEL		APPLICATION	BARRIER TEST	REQUIREMENT
1	• Used for **MINIMAL** risk situations • Provides a slight barrier to small amounts of fluid penetration • Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance.	Basic care, standard hospital medical unit	AATCC42	Water Impact ≤ 4.5g

2	• Used in **LOW** risk situations
	• Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking
	• Two tests are conducted to assess barrier protection performance:
	  • *Water impacting the surface of the gown material*
	  • *Pressurizing the material*
		Blood draw from a vein, Suturing, Intensive care unit, Pathology lab	AATCC42
			AATCC127
				Spray Impact ≤ 1.0g
				Hydrostatic Pressure ≥ 20cm

3	• Used in **MODERATE** risk situations
	• Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2
	• Two tests are conducted to test barrier protection performance:
	  • *Water impacting the surface of the gown material*
	  • *Pressurizing the material*
		Arterial blood draw, Inserting an IV, Emergency Room, Trauma	AATCC42
			AATCC127
				Spray Impact ≤ 1.0g
				Hydrostatic Pressure ≥ 50cm

4	• Used in **HIGH** risk situations • Prevents all fluid penetration for up to 1 hour • May prevent virus penetration for up to 1 hour • In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus. If no virus is found at the end of the test, the gown passes.	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods	ASTM F1670 ASTM F1671	Pass

Key characteristics of Trelleborg Engineered Coated Fabrics for gown applications:



- Conforms to:
- *EN 13795-1:2019*
- *EN 14126:2003*
- *AAMI PB70:2012 (Level 4)*
- *ASTM F2407*
- Launderable for 75+ washes
- No Bisphenol A (BPA) / No Conflict Minerals / No Halogenated Flame Retardants / No Heavy Metal Stabilizers / No Latex / No PFCs (Perfluorinated Chemicals) / No Plasticizer Phthalates / No POPs (Persistent Organic Pollutants) / No PVC (Polyvinyl Chloride) / No Triclocarban or Triclosan
- REACH & RoHS compliant
- ISO10993-10 Skin Irritation / classed as non-irritant; Skin Sensitisation – considered to be non-sensitiser
- ISO9001:2015 and ISO14001:2015 compliant manufacturing processess
- ISO10993-5 Cytotoxicity = < Grade 1

2-way stretch
For wearer comfort

Flame Retardent
16 CFR Part 1610 requirements for "Normal Flammability" – Pass

Waterproof
AATCC42
Spray Impact <0.05g
AATCC127
Hydrostatic Pressure >1500cm

Autoclave & Machine Washable
No delamination

Fungistatic
Contains an anti-fungal agent to control microbial deterioration; The products do not contain any nano materials.

Wipe clean
For infection control

Breathable
F1868 Part B
Ret >200 Pa.m2/W

Infection Barrier
ASTM F1671 (virus penetration) – Pass
ASTM F1670 (synthetic blood) – Pass

Weldable
Polyester fabric

UV Printing service available – further details on request

What makes polyurethane-coated fabric a good choice for gowns?

PVC FREE

- **Waterproof**, fluid-proof barrier for infection control
- **Autoclavable and machine washable** for reusability
- **Breathable** for wearer comfort
- **Lint-free**
- **Fit for purpose** – meets all required medical device standards

About Trelleborg Engineered Coated Fabrics

Part of Trelleborg Industrial Solutions AB, Trelleborg Engineered Coated Fabrics offers a range of technical textiles designed to meet all levels of performance for reusable surgical and standard hospital gowns.

Trelleborg Engineered Coated Fabrics offers a range of coating capabilites from its manufacturing sites in the US and UK, including: direct coating, lamination / hot melt and transfer coating.

Contact our technical sales team for product specifications:

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TrelleborgECF.com
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IT IS THE RESPONSIBILITY OF THE MEDICAL DEVICE MANUFACTURER TO ENSURE THAT THE FINAL GARMENT CONSTRUCTION PASSES REQUIRED BARRIER TESTING AND SEAM CONSTRUCTION TESTING.

References:
https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns *(accessed September 2020)*
https://www.gov.uk/government/collections/guidance-on-class-1-medical-devices accessed *(accessed September 2020)*