



**Learning about
Contamination Control - Part 3:
Choosing the Right
Cleanroom Garments**



Contents

Cleanroom Apparel	
Cleanroom Standard Guidelines	3
Guidelines Tables	
Non-Sterile	3
Sterile	4
Gowning for the Cleanroom	
What does gowning prevent?	5
Gowning Procedure	6
Choosing the Right Garments	
Disposable garments	7
SMS vs Microporous	7
Permanent garments	8
Elasticated vs stud fittings	8
Garments styles and features	9-10
Choosing the Right Headwear	
Caps	10
Masks	11
Goggles	12
Choosing the Right Footwear	
Shoes	12
Shoe Covers	13
Socks	13
Annex 1 Gowning Recommendations	
Grade A/B	14
Grade C/D	14

Cleanroom Apparel

Cleanroom Standard Guidelines

Individuals working in cleanrooms are required to follow strict protocols and wear special clothing such as coveralls, gloves, masks, and shoe covers. These garments are designed to prevent shedding of particles and to protect the cleanroom environment from human-generated contaminants.

Different cleanroom ISO classifications require different standards for gowning. Whether the cleanroom is sterile or non-sterile also changes what gowning items are required.

These guidelines should be strictly adhered to, to eliminate the risk of contamination.

Non-Sterile

CLASS 1 ISO 3	CLASS 10 ISO 4	CLASS 100 ISO 5 GMP GRADE A/B
Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Integrated Suit (Optional) Boots Facial Cover Gloves Frequency of Change: Daily
CLASS 1,000 ISO 6	CLASS 10,000 ISO 7 GMP GRADE C	CLASS 100,000 ISO 8 GMP GRADE D
Hood,Cap or Hair Cover Coverall or Frock Boots or Footwear Boots Facial Cover (Optional) Gloves Frequency of Change: 3 Times/Week	Cap or Hair Cover Frock Boots or Footwear Boots Facial Cover (Optional) Gloves (Optional) Frequency of Change: 2 Times/Week	Cap or Hair Cover Frock Footwear Boots Facial Cover (Optional) Gloves (Optional) Frequency of Change: 2 Times/Week

Contd.

Sterile

CLASS 1 ISO 3	CLASS 10 ISO 4	CLASS 100 ISO 5 GMP GRADE A/B*
Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Boots Facial Cover Gloves Frequency of Change: Per Entry
CLASS 1,000 ISO 6	CLASS 10,000 ISO 7 GMP GRADE C*	CLASS 100,000 ISO 8 GMP GRADE D
Hood Hair Cover Coverall Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood (Optional) Hair Cover Coverall Boots Facial Cover Gloves Frequency of Change: Per Entry	<p style="text-align: center;"><i>Garments in this environment are application specific.</i></p>

**Socks are required within GMP Grade A/B and C sterile cleanrooms where sterile medicinal products are being handled.*

Gowning for the Cleanroom

What does gowning prevent?

Gowning helps prevent contamination in the cleanroom. From head to toe, there are plenty of areas where gowning is critical, however, even with gowning there can still be some risk.

Most of the airborne particles emitted from cleanroom personnel migrate up through their cleanroom garment collars or down their legs when walking.

Note: *Colognes, deodorants, lotions, makeup and perfumes are NOT allowed in cleanrooms.**



*For information on cleanroom guidelines, please check out Part 5 of our guides
Part 5 - Preparing for the Cleanroom.

Visit our website at www.antistat.co.uk

Gowning Procedure

The following gowning procedure is for ISO 5. All products below are required to allow for full protection from contamination.

1. GLOVE LINERS



Recommended for Class 100 or better. Select gloves of proper size and don them following the glove donning procedure

2. FACEMASK



Select proper size and bend the nose-piece to ensure a snug facial fit. Check for leakage; nose and mouth should be covered

3. HOOD



Remove hood from packaging. Fully adjust to comfortable fit with the correct seal around the face area

4. GOGGLES



Wear goggles to cover the exposed eye area. Make sure goggles are placed firmly on the face and, if available, use adjusters on the strap to fasten accordingly.

5. SOCKS



Remove personal socks first and then remove cleanroom socks from packaging. Place over foot making sure sock is on securely

6. COVERALL



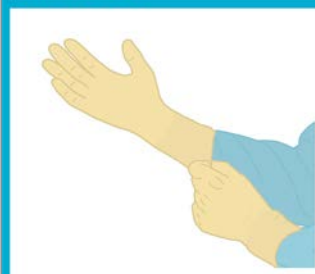
Remove coverall from packaging. Step into the coverall, ensuring upper garment and sleeves do not touch the floor. Tuck hood fully inside the collar and fasten up all zips.

7. SHOE COVERS



Remove shoe covers from packaging. Place over your shoes making sure they are fully covered from toe to heel.

8. GLOVES



Follow the glove gowning procedure, don gloves and ensure the cuffs cover the coverall sleeve. You are now fully gowned for the cleanroom

Visit our website at www.integritycleanroom.co.uk

Choosing the Right Garments

Disposable Garments

Disposable garments are a cost effective solution to gowning within the cleanroom. Manufactured from lightweight low-linting materials, disposable garments provide comfort, breathability and high performance.

This style of garment is also easily sterilised for superior contamination control.

SMS vs microporous

SMS (spunbond/meltblown/spunbond) and microporous disposable cleanroom garments are widely used in cleanroom environments to protect both the wearer and the products being manufactured from contamination.

SMS garments:

- SMS garments are made up of multiple layers of spunbond and meltblown polypropylene, which are thermally bonded together.
- They provide an excellent balance of breathability and particle filtration, making them suitable for a wide range of cleanroom applications.
- They are more durable than microporous garments, as they are less prone to tearing and puncturing.
- They may be more suitable for cleanroom environments with lower contamination levels, as they are less effective at blocking smaller particles.

Microporous garments:

- Microporous garments are made of a thin film coated with a layer of microporous particles, such as polytetrafluoroethylene (PTFE).
- They provide excellent particle filtration, as the microporous particles are able to block particles as small as 0.1 microns in size.
- They are less breathable than SMS garments, as the microporous particles do not allow as much air to pass through.
- They are less durable than SMS garments, as they are more prone to tearing and puncturing.

The choice between SMS and microporous disposable cleanroom garments will depend on the specific needs and requirements of the cleanroom environment and the products being manufactured. It is important to carefully consider the trade-offs between breathability, particle filtration, and durability when selecting cleanroom garments.

Permanent Garments

The higher quality material of permanent garments means they have higher protection and can be used in cleanrooms with more stringent ISO levels. Permanent garments are specifically designed and manufactured from lightweight, non-linting, monofilament polyester materials, providing a combination of comfort and protection.

These garments are also bespoke, meaning they can be adjusted depending on the needs/requirements of your cleanroom and procedures.

Elasticated vs stud fittings

Permanent cleanroom garments are often designed to have either elasticated or stud fittings to help ensure that they fit properly and remain secure on the wearer.

Elasticated fittings:

- Elastic bands or bands with an adjustable clasp are used to hold the garment in place.
- Elasticated fittings allow for a more flexible and comfortable fit, as they can stretch and adjust to the shape of the wearer's body.
- They may not be as secure as stud fittings, as they may loosen over time or if the wearer moves around a lot.
- They may be more suitable for clean rooms with lower contamination levels, as they are less likely to shed particles compared to stud fittings.

Studded fittings:

- Studded fittings use small snaps to hold the garment in place.
- They provide a more secure fit, as they do not loosen easily and do not rely on elastic bands.
- They may be less comfortable than elasticated fittings, as they do not adjust to the shape of the wearer's body and may feel constricting.
- They may be more suitable for clean rooms with higher contamination levels, as they are more effective at preventing particles from entering or exiting the garment.

The choice between elasticated and stud fittings will depend on the specific needs and requirements of the clean room environment and the preferences of the wearer. It is important to carefully consider the trade-offs between comfort, security, and particle shedding when selecting clean room garments with either type of fitting.

Garments styles and features

Garments can come in a range of styles with a large variety of features included which aid increased productivity within certain workplace environments. These include:

Coverall

Gives full body protection to the user and should be used in more stringent ISO levels.



Lab Coat

Quick and easy to put on. Great for moderately stringent ISO levels.



Isolation Gown

Worn over coveralls to protect user from contamination in low risk patient situations.



Hood

Allows for integrated protection from head hair particles.



Integrated Feet

Integrated feet allow for the maximum protection of the user and cleanroom.



Sleeve Protectors

Extra protection from handling contaminants in the cleanroom.



Overboots

Used in environments where extra protection is needed on the user's feet.



Bespoke Permanent Coverall Features

Here are a list of optional features coveralls can include:



Elasticated



Studded



Knitted



Lycra

Choosing the Right Headwear

Caps

Mob Caps are used within cleanrooms to protect the environment from hair particles. They are mainly for general hygiene use and for food/light industrial environments.

Pleated Cap

Pleated style caps are packed tightly meaning more can be stored at once.



Bouffant Cap

Bouffant Caps come flat packed so already open and easy to apply.



Masks

Masks are a critical part of stringent contamination control. Particles produced via the mouth can completely contaminate your workspace.

Face masks come in a variety of styles with different ties and loops depending on operator preference.

Headloop Face Mask

A headloop allows for easy application and can fit round all heads.



Earloop Face Mask

Loops go around the ears allowing easy application especially when using bouffant caps.



Tied Face Masks

The tied face mask allows for a more secure fit for the user to tighten as much as needed.



Duck Billed Face Mask

The mask size and shape improves breathability.



Beard Snood

Used in less stringent environments where the operator has facial hair.



Goggles

Goggles allow for supreme protection, each with different specifications and features. They are mainly to protect the user rather than the clean environment.

Sterile Goggles

Sterile goggles are specially engineered to guarantee high protection and comfort in controlled environments.



Elite Autoclave

These goggles are equipped with an extra wide panoramic view.



Superblast Autoclave

These goggles are resistant to high temperature and still fully functional after several autoclaving cycles.



Choosing the Right Footwear

Shoes

Cleanroom shoes protect the users feet from chemicals as well as protecting the cleanroom from contaminants created by feet.

Clogs

Lightweight and autoclavable, suitable for use in critical and aseptic environments.



Loafers

Slip-on, making them easy to apply and very breathable.



Safety Shoe

Completely metal free, suitable for ESD areas, food, hospital and hygiene sectors.



Visit our website at www.integritycleanroom.co.uk

Shoe Covers

Shoe covers allow for full protection within a cleanroom environment with a variety of styles to fit all needs.

Anti-Skid Covers

Includes sprayed latex anti-skid treads for enhanced safety.



Non-Woven Ant-Slip Covers

CPE deeply embossed for non-slip use and are also waterproof.



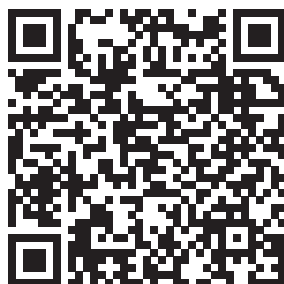
Polyethylene Covers

Affordable solution to shoe covers.



Socks

With the revised Annex 1, dedicated cleanroom socks are required to reduce contaminants from foot perspiration, especially in situations where shoe covers are not worn.



For our full range of apparel, follow the QR code to the left.

All permanent apparel can only be ordered via quote as they are custom made to customer specifications.

EU GMP Annex 1 Gowning Recommendations

Grade A / B:

Grade A signifies a critical area for high-risk operations such as aseptic processing lines or for making aseptic connections by providing initial air protection. Its background, Grade B, represents its preparation area. The revision of Annex 1 stipulates the following requirements in these areas:

- Use dedicated garments worn under a sterilised suit
- A sterile headgear which must enclose all hair (including facial hair)
- Sterile face masks
- Sterile eye coverings such as goggles that should fit the around the face
- Powder-free rubber or plastic sterile gloves*, **
- Sterilised footwear, such as over boots, clogs and shoes
- Use dedicated cleanroom socks

Grade C / D:

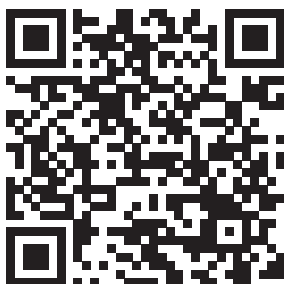
Grade C/D signify cleanrooms used for less critical stages in the manufacture of aseptically filled sterile products though may be used for the preparation/filling of terminally sterilised products.

- Cover hair, beards and moustaches with a beard snood
- Operators must wear single or two-piece trousers and high collar tunics (in grade C) and general protective suit (in grade D)
- Use a dedicated cleanroom sock in a Grade C cleanroom

Our expertise and knowledge within the pharmaceutical industry have led our team to develop an extensive range of products to meet the requirements of Annex 1 and assist you with the challenges this new revision brings.

**Annex 1 states that 'appropriately sterilised, non-powdered, rubber or plastic gloves should be worn while donning the sterilised garments' (paragraph 7.13).*

****For information on our glove range, please check out Part 4 of our guides
Part 4 - Choosing the Right Cleanroom Glove.**



For our page all about the newly updated Annex 1, scan the QR code to the left.

Visit our website at www.integritycleanroom.co.uk

Notes:



ISO 9001 QUALITY ASSURED

We are focused on meeting our customer's expectations and delivering exceptional customer satisfaction.

CUSTOMER FOCUSED APPROACH

With over 35 years' experience, our service culture is the very core of our customer's success.

STANDARD OF EXCELLENCE

From beginning to end our team of knowledgeable experts are here to help.

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