



THE ANSELL GUIDE TO CLEANROOM APPAREL

Cleanroom Classification

The FED-STD-209, Airborne Particulate Cleanliness Classes in Cleanrooms & Clean Zones was first published as FS 209 in 1963 by the Institute of Environmental Science and Technology (IEST). It became the foundation of the ISO 14644-1 standard: *Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration* which is used today. The FS 209 was

replaced by ISO 14644 in 1999 within the EU and in 2001 in the USA.

The ISO 14644 standard defines the classification number of a cleanroom dependent on the maximum allowable concentration of certain size particles per m³. The lower the ISO classification number the lower concentration of particles measured, and the 'cleaner' the cleanroom.

| ISO classification number (N) | Maximum allowable concentrations (particles/m ³) for particles equal to and greater than the considered sizes shown below | | | | | | FED-STD-209E |
|-------------------------------|---|---------|---------|------------|-----------|---------|---------------|
| | 0.1 µm | 0.2 µm | 0.3 µm | 0.5 µm | 1.0 µm | 5.0 µm | |
| ISO Class 1 | 10 | | | | | | |
| ISO Class 2 | 100 | 24 | 10 | | | | |
| ISO Class 3 | 1,000 | 237 | 102 | 35 | | | Class 1 |
| ISO Class 4 | 10,000 | 2,370 | 1,020 | 352 | 83 | | Class 10 |
| ISO Class 5 | 100,000 | 23,700 | 10,200 | 3,520 | 832 | | Class 100 |
| ISO Class 6 | 1,000,000 | 237,000 | 102,000 | 35,200 | 8,320 | 293 | Class 1,000 |
| ISO Class 7 | | | | 352,000 | 83,200 | 2,930 | Class 10,000 |
| ISO Class 8 | | | | 3,520,000 | 832,000 | 29,300 | Class 100,000 |
| ISO Class 9 | | | | 35,200,000 | 8,320,000 | 293,000 | |



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Choosing the right garment

The biggest contributor of contamination within a cleanroom is people. To avoid the introduction of contamination/particles into the clean environment it is imperative that anyone working within a controlled environment wears the most appropriate clothing for the cleanroom ISO classification. The suggested garments which should be worn within each of these classified areas are:



Coveralls

- Should offer total body coverage.
- Be comfortable for the wearer for extended periods of time.
- Have a sealed zip fastening front.
- Should have elasticated cuff and ankle openings.



Hoods

- Should provide full coverage of the wearer's head.
- Should have an elasticated face opening.



Overboots

- Should have flat soles.
- Should provide total coverage of the foot and lower leg.



Gloves

- A variety of gloves manufactured from Latex, Nitrile, Polyisoprene, Polychloroprene or Vinyl can be used.
- They must be powder-free if used within the Cleanroom.



Face Masks

- Can be either disposable or re-usable dependent on application.
- Should provide full coverage of the mouth and nose.



Coats

- Can be supplied with a centre or side fastening zip or a stud fastening front closure.
- The cuffs can have various fastenings including stud, elastic and Lycra.



Overshoes

- Should be supplied with flat soles.
- Should provide coverage of the foot.



Undergarments

- Comprise of short or long-sleeved tunics and trousers.



Bouffant Caps

- Should provide coverage of the wearers hair.

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Which garment do I choose for which ISO classification?

The IEST-RP-CC003.4 standard for *Garment system consideration for cleanrooms and other controlled environments*, recommends the best practice for the gowning of personnel as a critical aspect of cleanroom contamination control. Outlined below is guidance for the selection of garments or apparel and accessories appropriate for use in cleanrooms and controlled environments.

| ISO EN 14644-1 2015 Classification Number | | | | | | | |
|---|-------|---|---|---|---|---|---|
| APPAREL | 1 & 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Hood | ○ | ✓ | ✓ | ✓ | ○ | ○ | ○ |
| Coverall | ✓ | ✓ | ✓ | ✓ | ✓ | ○ | ○ |
| Overboots | ✓ | ✓ | ✓ | ✓ | ✓ | ○ | ○ |
| Overshoes | ✗ | ✗ | ✗ | ✗ | ○ | ✓ | ○ |
| Undergarments | ✓ | ✓ | ✓ | ✓ | ○ | ○ | ○ |
| Coats | ✗ | ✗ | ✗ | ✗ | ○ | ✓ | ✓ |
| Facemasks | ○ | ✓ | ✓ | ✓ | ○ | ○ | ○ |
| Gloves | ✓ | ✓ | ✓ | ✓ | ○ | ○ | ○ |
| Bouffant Caps | ○ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

Key: ✓ Recommended ○ Application Specific ✗ Not Recommended

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Understanding the composition and structure of cleanroom garments

The most recent IEST-RPCC003.4, Garment system consideration for cleanrooms and other controlled Environments standard lists six types of nonwoven fabrics for use in cleanrooms and other controlled environments, and describes each fabric as follows;

1. Spunbonded or thermal bond

A nonwoven fabric typically made from polypropylene in a relatively open structure. More commonly used in bouffant caps, shoe covers etc. This type of non-woven fabric does not demonstrate high barrier performance.

2. Flash spun

A nonwoven fabric made of high-density polyethylene continuous fibres. Flash spun non-wovens have some barrier properties and are splash-resistant to water.

3. Melt blown

Made from continuous polypropylene microfibrils and used in composite structures of many types of face masks because of its high filtration efficiency and repellence. Melt blown fabric does not have adequate strength to be used alone for garments.

4. Spunbonded/melt blown/spunbonded (SMS)

A laminate structure made from polypropylene continuous fibres, SMS offer barrier protection and comfort.

5. Film laminate

A spunbonded layer laminated to nonporous films. Demonstrates particle, blood and chemical barrier properties but lacks air and moisture permeability.

6. Microporous film laminate

A laminate made from a spunbonded layer and a microporous film for improved barrier properties. This laminate is a splash-resistant and a blood barrier. Microporous film laminate is optimal for use in surgical areas and critical environments.

When selecting garments for cleanroom use, depending on the specific application, the IEST standard recommends evaluating the fabric properties including testing for (selecting those relevant to the fabric type);

- Cleanliness and cleanability
- Electrostatic properties
- Biological properties
- Durability
- Comfort
- Opacity
- Particle filtration efficiency
- Microbial penetration
- Chemical compatibility
- Fluid resistance

Construction of cleanroom garments is another important consideration, and the IEST standard outlines recommendations for thread and seam structure. Seams for cleanroom garments should be joining seams to avoid free-air/particulate passage from the inside of the garment to the outside environment. The IEST standard recommends for the construction of cleanroom garments that they are constructed using a bound joining seam, as shown in figure 1.

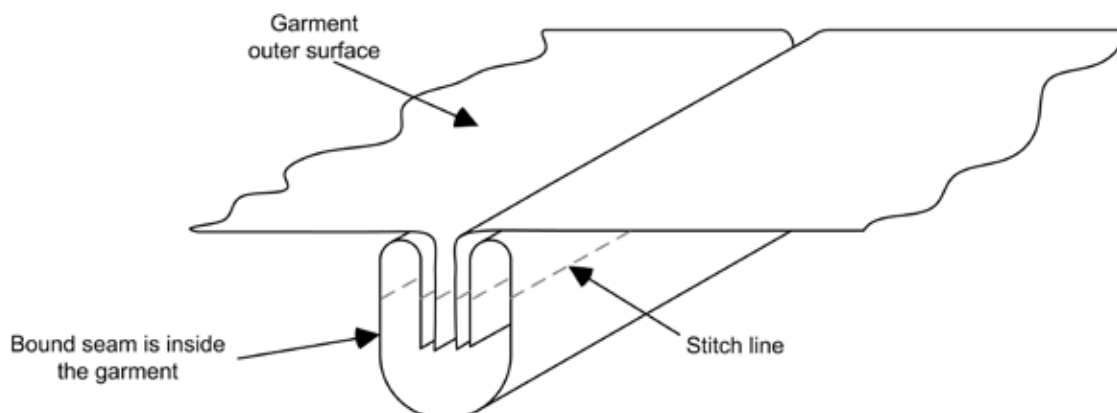


Figure 1

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Recommended cleanroom garments

BioClean-D™ Disposable cleanroom garments are manufactured according to the recommendations set out within the IEST-RP-CC003.4 standard, using the most effective barrier fabric and the best seam joining for containment of particles and fibres.

Our BioClean-D™ garments are:

- ✓ Lightweight
- ✓ Low-linting
- ✓ Durable
- ✓ Microporous
- ✓ Bound seams
- ✓ Anti-static (EN 1149-5 compliant)
- ✓ Tested to ASTM F739-99A against cytotoxic drugs
- ✓ Non-radioactive
- ✓ Available in gamma irradiated versions
- ✓ Made from CleanTough™ material

What is CleanTough™ material?

- Double laminate microporous fabric
- Spun bonded non-woven polypropylene layer laminated with a film of polyethylene
- This construction is necessary to allow comfort and flexibility during use and protection against fine sprays and particles
- Can be sterilized by Gamma Irradiation



Magnified x200



Magnified x400

The user should assess the choice of apparel and accessories carefully to ensure these are suitable for the Class of cleanroom, the nature and duration of the task.

This document is only intended as a general guide and should not be construed as a recommendation of the apparel required for a particular Class of cleanroom. Please see the Standard Operating Procedure of the cleanroom for the apparel required, the gowning procedure and change frequency.

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