Cleanroom business

union micronclean

Email

Info@unionmicronclean.com

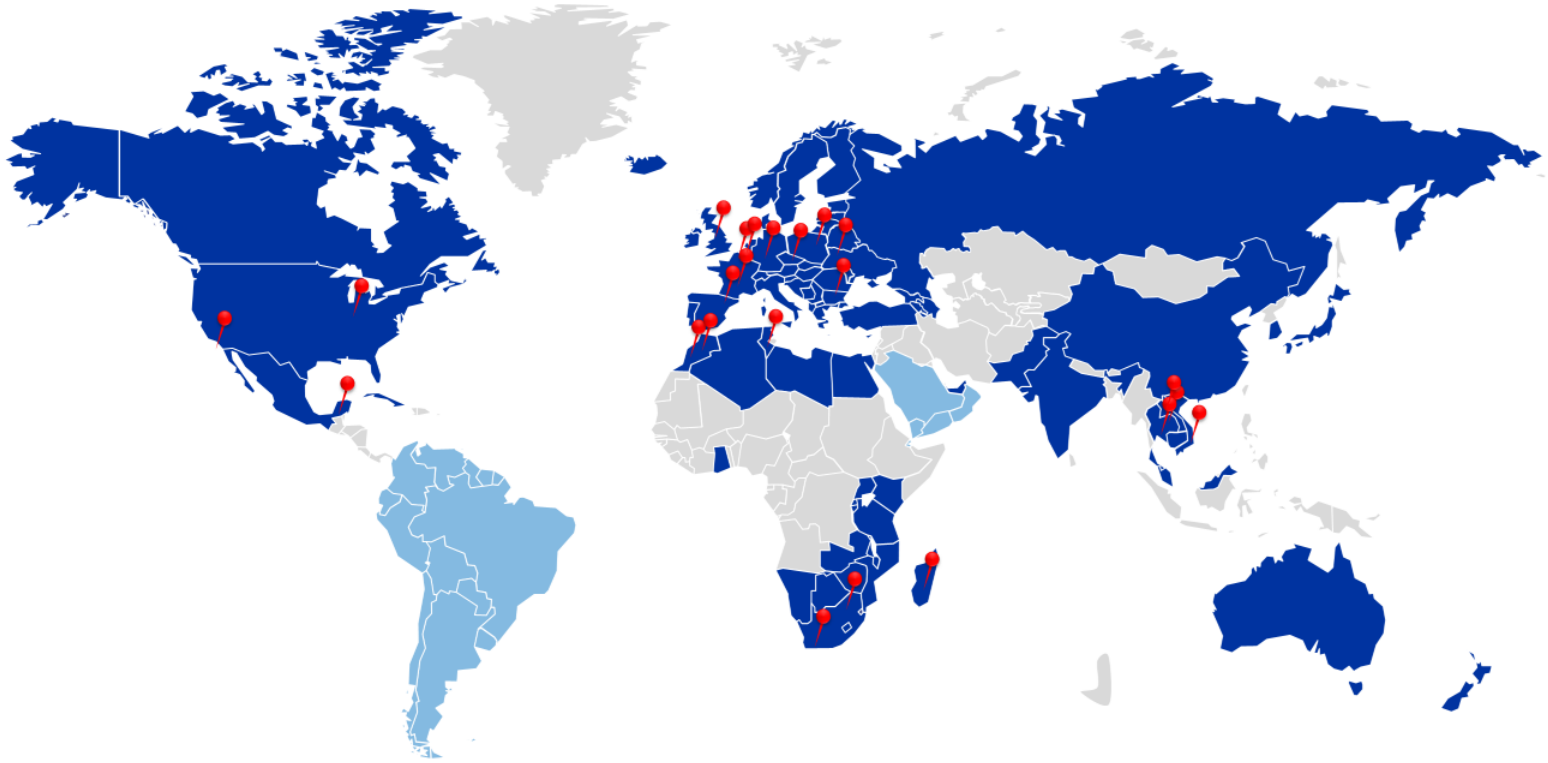
Call

Tel : (66-2) 710-7786
Fax : (66-2) 710-7793

Address

205 Moo 4 Sukhumvit Road (k.m. 39.5), Bangpoo Mai,
Muang District, Samutprakan, Thailand 10260

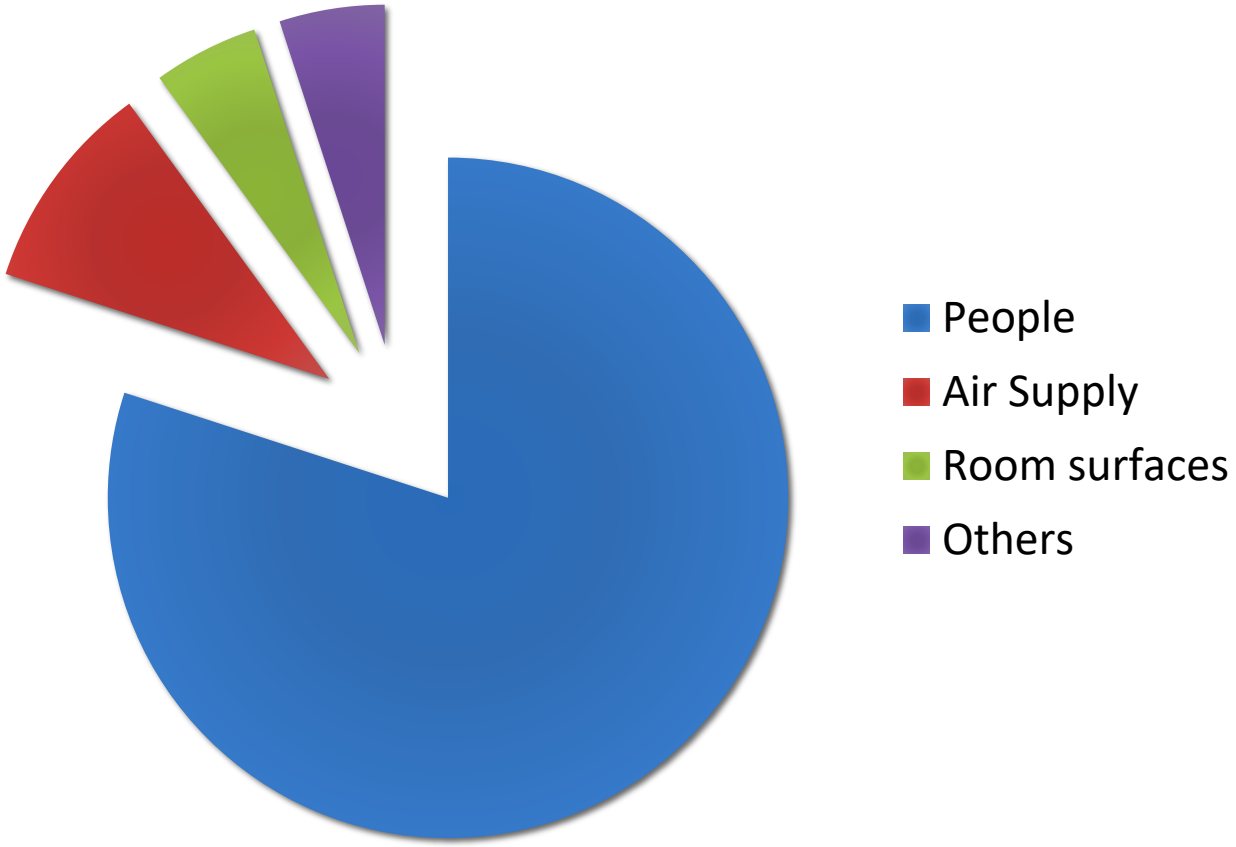
alsico group overview



alsico group

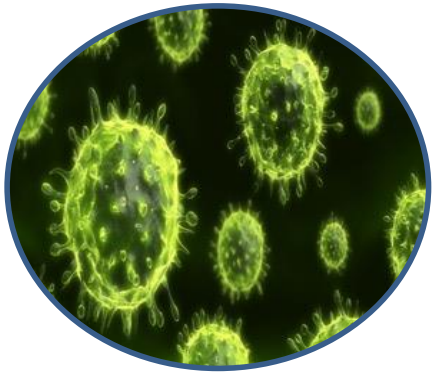
Source of contamination

- ✓80 % of the impurities present in a cleanroom originate from people



Cleanroom Classes according to IEST-RP-CC003.4

USD FED STD		100.000	10.000	1.000	100	10	1
ISO		ISO 8	ISO 7	ISO 6	ISO 5	ISO 4	ISO 3
GMP EU		D	C		A/B		
Maximum Particles/ m3	≥ 0,1 µm			1.000.000	100.000	10.000	1.000
	≥ 0,2 µm			237.000	23.700	2.370	237
	≥ 0,3 µm			102.000	10.200	1.020	102
	≥ 0,5 µm	3.520.000	352.000	35.200	3.520	352	35
	≥ 5 µm	29.300	2.930	293	29		



VIRUS
(0,003-0,05µm)

BACTERIA
(0,03-10µm)

HAIR (**100**µm)

Source of contamination

- ✓ Numbers of Particles (> 0,5 µm/min) dispersed by human (Non Smoker/Smoker):
  - ✓ Speaking :15.000 / 30.000
  - ✓ Coughing :700.000 / 1.400.000
  - ✓ Sneeze : 1.400.000 / 3.000.000
- ✓ Numbers of Particles (> 0,3 µm/min) dispersed by human:
  - ✓ Sitting: 500.000
  - ✓ Working sitting position : 1.000.000
  - ✓ Physical exercises: 10.000.000 - 30.000.000

- ✓ Standard garments in 100 % Cotton or Polyester/cotton and Polyester/ wool are generating big amounts of particles
  - ✓ Cotton : 1.000.000 particles/min
  - ✓ Pes/ cotton : 350.000 particles/min
  - ✓ **Micropolyester only 10 – 200 particles/min**

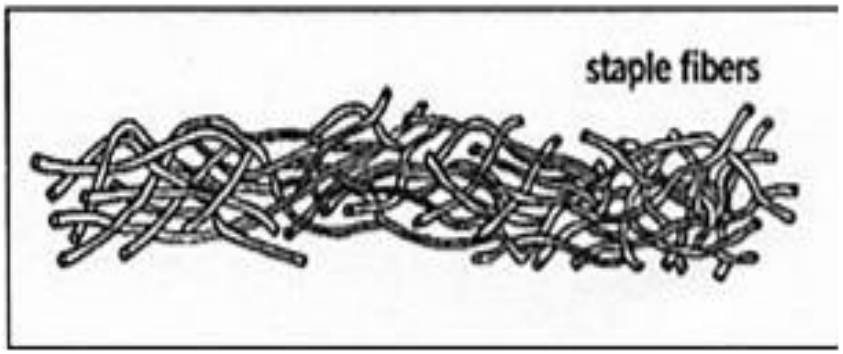
What should a cleanroom garment do?

- ✓ **Purpose:** Protect the cleanroom and the products against the particles from the operators and their garments.
- ✓ **Cleanroom garments are not Personal Protective Equipment (PPE)**
- ✓ Our cleanroom garment solution will reduce:
    1. **Microbial Count**
    2. **Particulate Count**
- ✓ All features of a cleanroom garment are produced in such a way to achieve 1 goal:

CONTAMINATION CONTROL

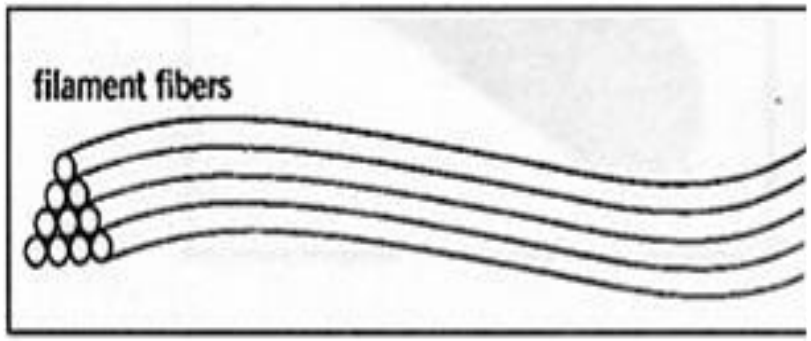
เส้นใยธรรมชาติ(Natural Fiber)

เส้นใย สั้น

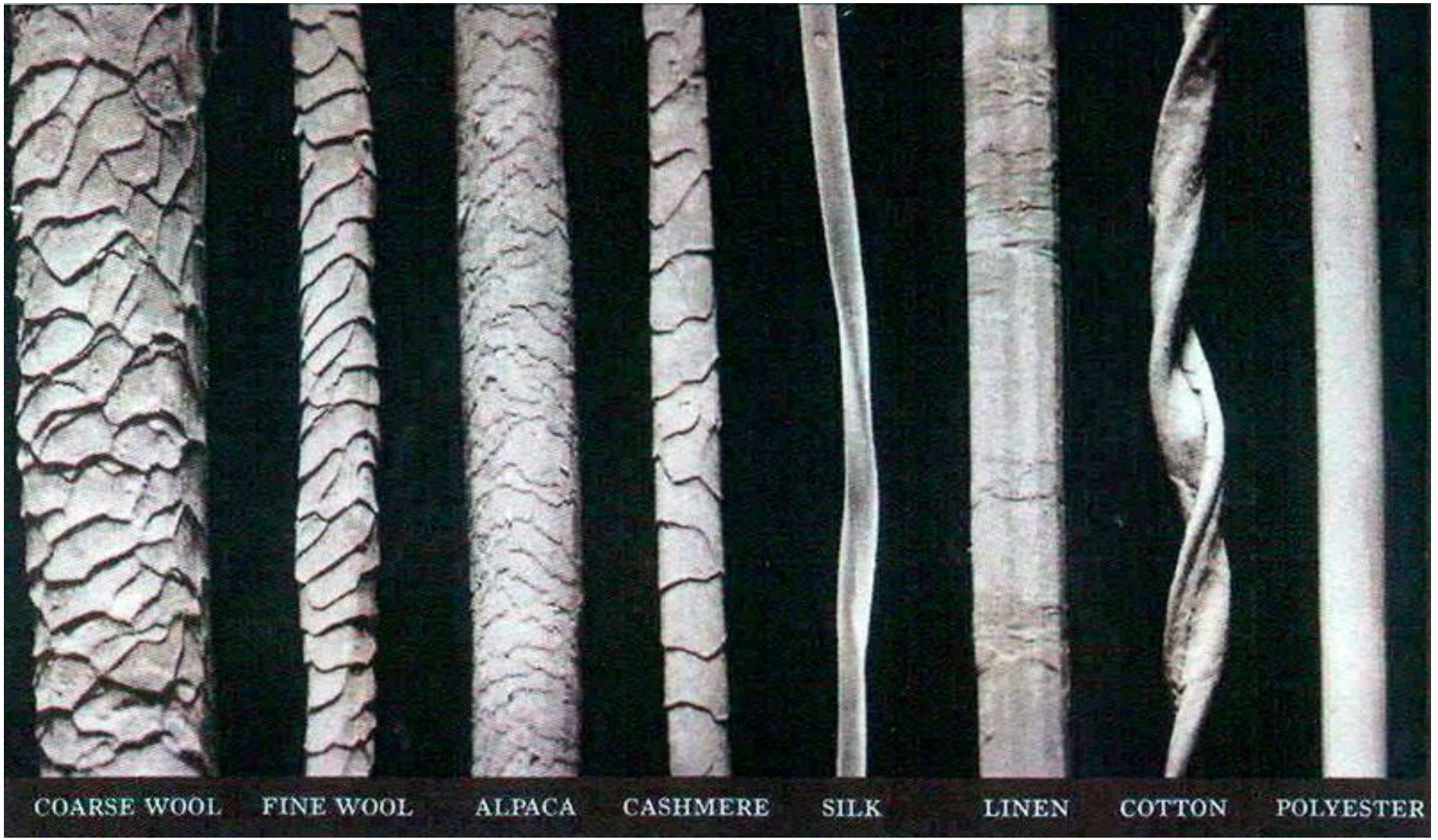


เส้นใยสังเคราะห์

เส้นใย ยาว



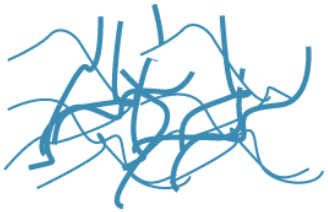
Cleanroom fabric



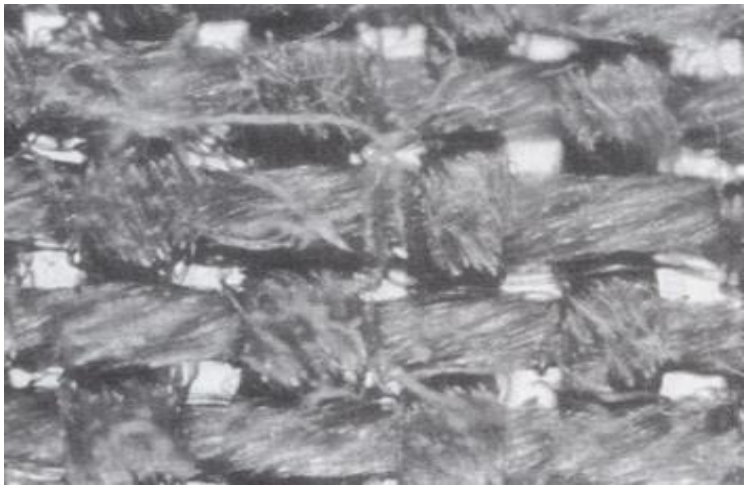
Cleanroom fabric

- ✓ Mono filament
- ✓ Micro-Polyester
- ✓ Less than one Denier (9000m<1g)

BCF FIBER

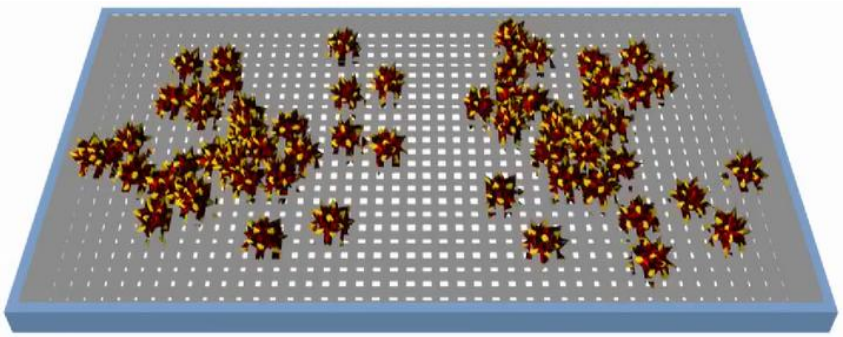


STAPLE FIBER

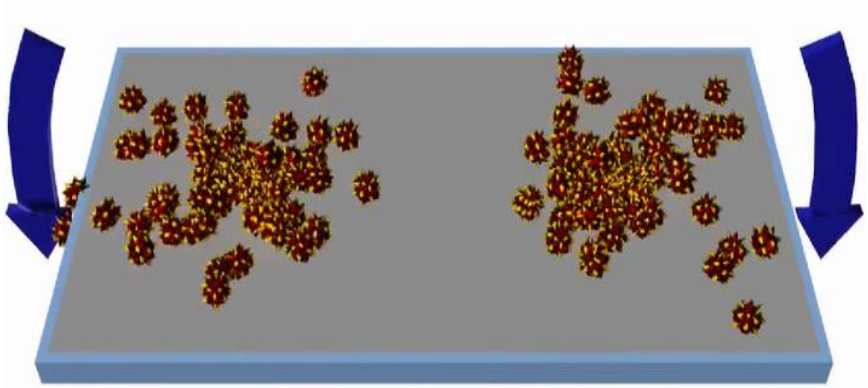


Cleanroom fabric

- Breathable fabric



- Non-breathing fabric



Cleanroom fabric

Carbon Yarn

Purpose: protect the product from electrostatic discharge and contamination

- ✓ Static electricity makes particle to stick to coverall, operator and critical surfaces
- ✓ Safety of operators & equipment

Medical cleanroom

ISO 14644-1

Classification of air cleanliness

Federal Standard 209

The first available and most readily understood standard was Federal Standard 209 (1963) which recorded cleanliness levels by considering the number of particles ≥0.5 µm per ft^3. This simple classification system, with some appropriate types of cleanroom operations, is shown below.

Federal Standard 209 (1963) Cleanroom Classification System

FS209 (1963) Classification	1	10	100	1000	10000	100000
No. of Particles/ft3 ≥0.5µm	1	10	100	1000	10000	100000
Cleanroom Manufacturing Operations	Integrated Circuit	Semi conductor	Injectable medicines	High quality optical equipment, Gyroscopes	High grade gearing, precision pneumatic equipment	General optical work, assembly of electronic equipment

Several changes to FS 209 were made over the years and the final version FS209E, utilised metric nomenclature i.e. particles per m^3 (1 m^3 = 35.2 ft^3). Consequently, 100 particles per ft^3 became 3520 particles per m^3.

With the rapid increase in the global use of cleanrooms for the production of pharmaceutical products and microelectronic devices the requirement for an agreed international standard became apparent and International Standard ISO 14644[ref 3] was developed.

ISO 14644-1

Classification of air cleanliness

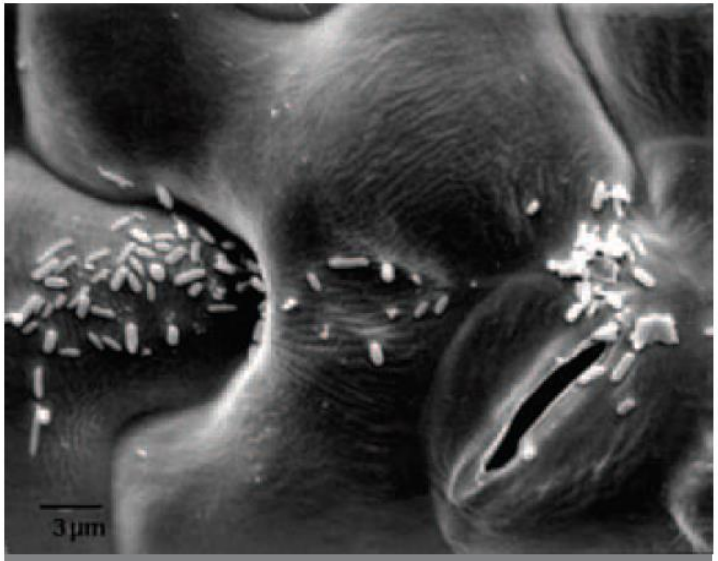
ISO 14644-1 airborne particulate classes for cleanrooms and clean zones at the particle sizes given

ISO Classification Number	Maximum concentration limits (particles/m³ of air) for particles equal to and larger than the considered sizes shown below					
	0.1µm	0.2µm	0.3µm	0.5µm	1µm	5µm
ISO 1	10	2				
ISO 2	100	24	10	4		
ISO 3	1,000	237	102	35	8	
ISO 4	10,000	2,370	1,020	352	83	
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7				352,000	83,200	2,930
ISO 8				3,520,000	832,000	29,300
ISO 9				35,200,000	8,320,000	293,000

Contamination Control and Staff

The normal microbial skin flora, which may include potential pathogens such as *Staphylococcus aureus*, will also be present on this cell debris and viable micro-organisms will leave the body surface as a consequence of desquamation. Most micro-organisms found in cleanrooms are found in the air, rafted on particles of skin.

A healthy male can disperse to the air approximately 1000 bacterial cells per minute during active exercise with an average of around 200 cells per minute, females generally disperse less.



Micro-organisms on skin cells

Normal human physiology will therefore continuously produce significant quantities of both inert and viable particles; however age, health, activity and clothing will all have an influence on total dispersion.

The temperature differential between the wearer and environment also has a large impact on the actual number of particles liberated from the body into the cleanroom.

Normal room temperature is around 20°C and normal body temperature 37°C, this temperature difference generates warm-air convection currents which rise from the body surface into the cooler room air.
These rising convection currents carry with them large numbers of particles into the room air which disperse and normally fall by gravity (although in a unidirectional flow area the particles are purged from the room by the moving, filtered air-flow).

ESD properties

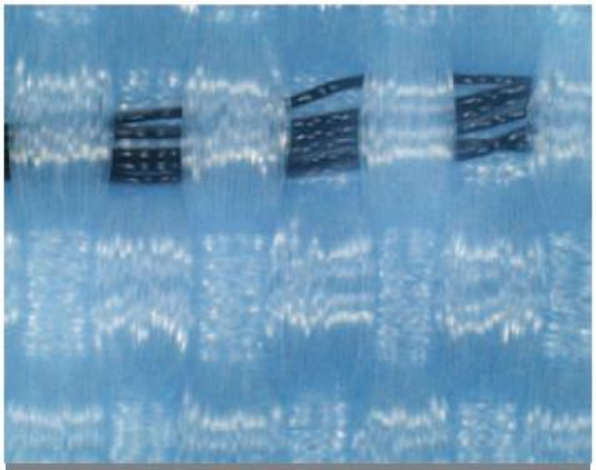
2.3

ESD Requirements and Standards

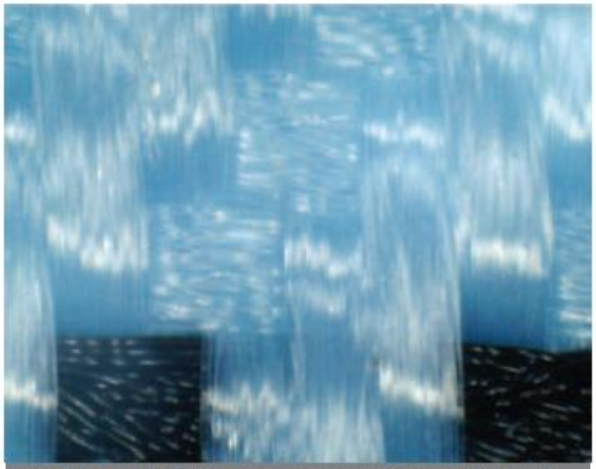
Control of electro-static discharge (ESD) is critical in any manufacturing area where products may be damaged by static discharge or where a fire risk is present. High-grade surface finishing operations may also require ESD control.

Fabrication of electronic devices and the assembly of medical devices are the main cleanroom manufacturing operations which most often consider this hazard.

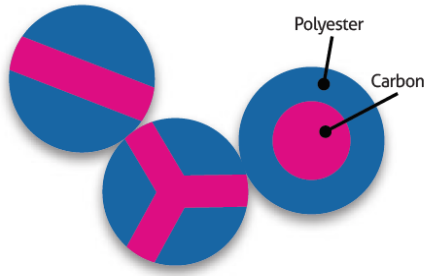
ESD controlled area



Photomicrograph of plain weave cleanroom fabric with ESD yarn



Photomicrograph of twill weave cleanroom fabric with ESD yarn



Carbon encapsulated in polyester producing different configurations of conductive yarns

Triboelectric charging is a phenomenon which most people experience from time to time when a significant static charge builds up on their clothing, often due to rubbing together synthetic fibres.

Once the potential is high enough and a route to earth becomes available the charge can dissipate violently and the electric shock sometimes experienced when applying a key to a car lock is a common example of this effect. As well as being uncomfortable the discharge of high voltage sparks in this way can cause a fire hazard and can also cause extensive damage to microcircuits, which may not be immediately evident.

During use static electrical charge accumulates in this way on cleanroom garments made from synthetic fibres and migrates to the conductive yarns.

This charge may then be dissipated by the conductive yarns being grounded to earth or by corona discharge into the air.

Cleanroom garment making practice

Construction

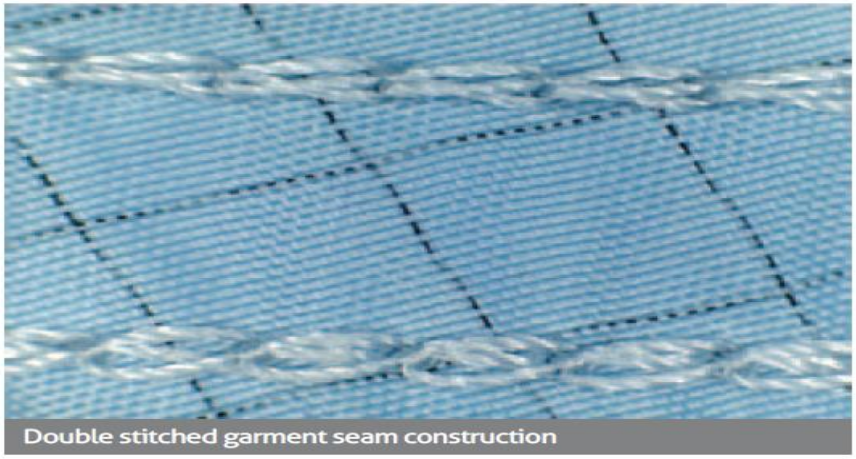
Specialised manufacturing techniques must be employed when constructing contamination control clothing. These methods are more complicated than those used to manufacture normal workwear but are required to minimise the possibility of contamination occurring from the garment itself.

1) Sealed edge fabric panels.

Fabric panels are cut using a controlled and graded pattern before being sewn together to manufacture the garment. The edges of the panels are sealed before sewing begins and this ensures that no fibre break-out occurs within the enclosed seams.

2) Fully enclosed seams.

All seams are totally enclosed using a double stitching technique. This method encapsulates all the cut and sealed edges of the fabric and is in sharp contrast to overlocked seams used for most garment construction.



Double stitched garment seam construction

3) Sewing thread.

All sewing thread used is silicone-free continuous filament polyester. Normal sewing threads are not suitable as they are manufactured from short staple filaments which can produce fibres and particles.

PPE categories

Category III garment CE label

In addition the garment type indicates the kind of protection offered by protective clothing as defined by European Standards [ref 2].

Category III PPE includes six Types

Type 1 - Gas-tight clothing

Type 2 - Non gas-tight clothing

Type 3 - Protection against pressurised liquid chemicals

Type 4 - Protection against liquid aerosols

Type 5 - Protection against airborne solid particulate chemicals

Type 6 - Limited protection against mist

It is important to note that if disposable garments are required for PPE then advice must be obtained from a Health and Safety professional to confirm the correct choice of clothing.

CONTAMINATION CONTROL

Minimizing the risks of contamination

How to obtain contamination control?

A. Working in a controlled manufacturing environment

B. Using the correct cleanroom fabric

C. Using the correct sewing methods

D. Using the correct garment design

E. Using the correct outer garment in combination with the correct inner garment

All features of a cleanroom garment are produced in such a why to achieve 1 goal:

CONTAMINATION CONTROL

Manufacturing environment

- ✓ Garments are made in controlled area
- ✓ Operators are required to remove make-up to work
- ✓ Operators are trained only for cleanroom garment