Hand Protection
Key Selection Criteria

The Fisher Scientific channel offers a variety of quality-tested gloves that are suitable for use in ISO Class 3, 4 or 5 cleanrooms. Our gloves are available in various materials, sizes, and packaging to meet your specific needs. Changing or upgrading gloves in a critical environment requires time and in-depth analysis. The wrong choice can severely impact personal safety, product quality, and yield.

Here are the top selection criteria to consider:

Cleanroom Classification

Choose gloves based on your cleanroom classification so that particulate, extractable, and non-volatile residue (NVR) levels are appropriate. Depending on the manufacturer, it is clearly stated on the packaging which ISO levels the gloves are compatible with or it mentions “critical” or “controlled” as more general indications.

There are two international standards used for cleanroom classification, ISO 14644-1 and GMP, which measure the maximum permitted number of particles and microorganisms/m³. These supersede Federal Standard 209E which was cancelled but is still used as a reference in some industries.

Comparison between the 209E, ISO 14644-1, and GMP cleanroom classifications

Particles		Particles & Microorganisms	Cleanliness Level
Federal Std. 209E*	ISO 14644-1	GMP	
1/m³	ISO 3		Ultraclean
10/m³	ISO 4		↓
100/m³	ISO 5	A (sterile), B	
1000/m³	ISO 6		
10,000/m³	ISO 7	C	
100,000/m³	ISO 8	D	Dirty

*Clean not classified

Testing and Labelling

While most controlled environment gloves provide protection of the product and the production process, the operators themselves may also need protection from hazardous material. Consider a glove’s personal protective properties and be aware that multiple gloves may be needed to satisfy all workplace requirements.

Summary of key test data for cleanroom gloves

Personal and Product Safety		People	Production		Lot Specific
Regulation/Norm	Testing/Documentation		Sterile	Non-Sterile	
(EU) 2016/425	PPE regulation (Declaration of Conformity)	x			
EN420	Protective gloves - General requirements and test methods	x			
EN ISO 374-1	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks	x			
EN ISO 374-5	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organism risks	x	x	x	
IEST-RP-CC005	Particle release and extractable matter (Certificate of Analysis)		x	x	
EN ISO 11137-1	Sterilization of Health Care Products (Certificate of Irradiation)		x		x

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Material

Material	Material Properties	Cleanroom Suitability
Vinyl/PVC	Low tensile strength and elongation. Reduced flexibility and ergonomics. High non-volatile residue (NVR) wet particle counts.	For use in cleanrooms with low sensitivity to particle contamination and low risk of exposure to microbiological hazards.
Natural Rubber Latex	Superior tensile strength and good elastic properties. Low in particle and ionic extractables. Risk of allergic reactions.	For cleanroom applications where there is a need to avoid particulates and ionic contaminants and that require enhanced grip, flexibility, and high wearing comfort.
Synthetic Latex, e.g. Nitrile, Neoprene, Polychloroprene, Polyisoprene	Good elongation and tear resistance. Superior abrasion resistance. Very low ionic and particle residues. No latex proteins, so reduced risk of allergic reactions.	Compatible with the highest cleanliness level requirements in terms of low particulate and ionic contaminants. Excellent barrier protection and puncture resistance for critical applications. Suitable for gamma-irradiation.

Performance

A glove's particle and ionic extractable counts must meet your cleanliness requirements. Compliance to essential regulatory standards can be found in the manufacturers' specifications. Other key performance factors to be considered are durability, strength, and barrier protection, along with dexterity, size, length, and overall wearing comfort.

Sterility

Gloves for sterile environments should be processed in certified cleanrooms, packaged in poly pouches or wallets, and sterilized by gamma irradiation or any other appropriate method in order to achieve an acceptable sterility assurance level (SAL). The common acceptable level is a SAL of 10^{-6}, which is regularly used for the terminal sterilization of medical devices. At this level the probability of finding a non-sterile unit is 1 in 1,000,000.

Other

If static electricity is of concern in your workplace environment, check if the gloves are suitable for electrostatic discharge (ESD) resistance.