More and more industry segments have to manufacture their products under clean conditions. Whereas 50 years ago only the emerging semiconductor industry, aerospace technology and perhaps the nuclear industry used cleanrooms, today there are numerous industry segments in which "clean" or at least "controlled" ambient conditions are required for production. These cleanrooms need to have suitable production equipment, including of course all those components that are built into the machines and systems in the cleanroom. In most cases conventional catalogue and series components are perfectly adequate for pneumatic and electric handling components. Ultimately, all suppliers of machine components and parts must prove that their products are appropriate for use in a cleanroom.

This white paper provides answers to the questions:
- What is a cleanroom (definition, norms, standards)?
- How are products tested for suitability for cleanrooms?
- In which areas and applications are cleanrooms necessary?
- Under which conditions are series products suitable for cleanrooms?
What is a cleanroom?
The concentration of airborne particles in cleanrooms is kept below a specified limit through the use of ingenious ventilation technology. These limits are defined in the ISO 14644 series of standards. ISO 14644-1:1999 was the first and fundamental standard of this series. It was originally based on US Federal Standard 209 E issued in 1988, and has been continuously revised and supplemented since its initial publication. Technical committee ISO 209, “Cleanrooms and associated controlled environments”, is responsible for its standardisation.

Even today, the “old” classifications in accordance with US Federal Standard 209 are still quoted. This standard was the definitive guide for almost two decades. It is distinguished by its clear representation of concentrations of particles using the reference size of 0.5 µm. In 2001, US Federal Standard 209 was withdrawn in order to make way for the new ISO 14644-1.

<table>
<thead>
<tr>
<th>Classification according to ISO 14644-1</th>
<th>Maximum particle concentration (particles per cubic meter of air)</th>
<th>Classification according to US Federal Standard 209 E</th>
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Figure 1: ISO 14644-1 standard in comparison with US Federal Standard 209 E

Figure 1: ISO 14644-1 standard in comparison with US Federal Standard 209 E

How are products tested for suitability for cleanrooms?
There is currently no internationally recognised test or qualification method. Each manufacturer can develop its own test method for classifying production equipment and publish the data obtained with that method. As long as the manufacturers describe and explain their individual methods, there is nothing wrong with this – with one exception: it is virtually impossible to compare products among one another with respect to cleanroom compatibility.

In order to curb this proliferation and to ensure more transparency, technical committee ISO 209 has been developing an internationally valid procedure since 2012 which is scheduled to be defined within the next two years in ISO 14644-14, “Assessment of suitability for use of equipment by airborne particle concentration”. This supplement to ISO 14644 is likely to closely follow the German directive VDI 2083-9.1.

It will therefore just be a matter of time before a consistently applicable qualification method will be available.

Assigning components to the various cleanroom classes according to ISO 14644-1 indicates the suitability of those components for a particular cleanroom class. This means that the components comply with the specified cleanroom class during operation and the concentration of airborne particles does not exceed the defined level.

Furthermore, the use of production equipment in the cleanroom demands first-class expert knowledge. For example, it is important to bear in mind that an active, moving component influences the cleanroom differently than an inactive component.
How are products qualified in accordance with VDI 2083-9.1?

With the direct measuring procedure in VDI 2083-9.1, the test object is first of all scanned by a particle detector in a so-called "mini-environment" which complies with ISO 14644-1 class 3, in order to pinpoint critical areas. These are the places where most of the particles are generated, for example the area immediately around the piston rod seal on pneumatic cylinders.

The advancing and retracting motion results in particles being discharged into the environment. Average particle concentration is measured at this point for a period of 100 minutes. The cylinder is operated with 80% of its maximum permissible load.
In which areas and applications are cleanrooms necessary?
The requirements for production technologies and products – smaller, faster, more precise – mean that manufacturing and processing techniques need to be constantly refined. At the same time, for manufacturing to be economically efficient, it is important that mass production comes with premium quality. Cleanrooms that are dust-free and germ-free have therefore become essential for many industry segments. As a result, applications where cleanroom technology is used have been increasing at an above-average rate for years now.

Classic examples of this are the production of microchips in the electronics industry and miniaturised products in precision mechanics. Other applications include rooms in hospital clinics, medical instruments, equipment and products that need to be aseptic in order to avoid endangering the health of patients by infected wounds for example. In food and drinks production or with cosmetic or medicinal products, dust or microorganisms are equally undesirable visitors since such contamination may impair the quality and shelf life of the products. In order to ensure that analyses are meaningful and genuine, it is essential that processes in research labs are carried out in air that is free of foreign particles.

Today, state-of-the-art cleanroom technology makes a considerable contribution to the safety of people and the environment. The importance and necessity of cleanrooms are forecast to increase in the future, opening up new areas of applications and usage which will be suitable for production.

Why are series components perfectly adequate for automation in cleanrooms in many cases?
The majority of today’s requirements for cleanroom compatibility can be met by series products. These parts do not even need to be packaged specially for the cleanroom – an expensive process that is usually completely unnecessary. However, it is essential to consider where exactly the components will be used. Every application has different areas with varying requirements in terms of cleanroom class. Experience has shown that almost any piece of equipment designed for cleanroom use can be assembled and shipped in a normal environment. The final cleaning procedure takes place at the destination site.

The only decisive criterion is that the products used comply with the specified cleanroom class during operation. This should be qualified by taking relevant measurements e.g. as per VDI 2083-9.1 or in future ISO 14644-14.

![Figure 6: Where a piece of equipment is used is decisive for the required cleanroom class](image-url)
Pneumatics in cleanrooms

Pneumatic drives are highly suitable for use in cleanrooms. By design, they are (in ideal condition) zero leakage systems.

In a cleanroom specified according to ISO 14644, airborne particles in the ambient atmosphere may not exceed a defined quantity according to ISO classes 1 to 9. With a pneumatic cylinder, particles are mainly generated by escaping compressed air (leakage) or at sealing systems, piston rods or guide bearings due to friction.

In case of double-acting pneumatic cylinders without any additional guide, the places at which leakages may occur are the two threaded connectors that connect the tubing lines with the front and rear piston chambers and the seal on the piston rod.

Faulty or leaking connections between the piston tube and the bearing and end covers of a cylinder ought not to occur these days – and if they do, it is safe to assume that one of the components is defective. This type of leakage is therefore not considered below.

If connectors are correctly screwed in, then leakage should not occur there. However, all types of connectors are subject to different levels of friction between the tube and the connector. This type of friction is caused by air pulsating inside the tube and, in case of moving cylinders, by movement of the tube.

Another source of particle emissions may be the piston rod advancing and retracting. The piston rod seal slides along the piston rod, thereby discharging particles. Some of these particles will be flung into the environment due to the dynamic process while others will become stuck in the lubricant film on the piston rod. A properly lubricated piston rod to which a visible but non-dripping lubricant film has been applied does not constitute contamination in the sense of airborne particles. However, excessive grease that has accumulated on the piston rod or on the piston wiper during the course of operation needs to be wiped off immediately in the cleanroom during repeated visual cleanliness checks.

Series pneumatics in the cleanroom up to ISO class 4

The degree of particle emissions tends to increase with the size of the piston rod diameter. With the most commonly used cylinder sizes up to a diameter of 50 mm, these particle emissions are for the most part negligible so that the cylinder in question can usually be approved for ISO class 7 cleanrooms. At best pneumatic drive components can be operated in an ISO class 5 or even ISO class 4 cleanroom – without making any engineering changes.

By making engineering changes such as a double piston rod seal or additional vacuum extraction close to the piston rod seal, a pneumatic cylinder can also be rendered suitable for an ISO class 4 cleanroom. This however should be a rare exception since permanent vacuum extraction during operation will result in extra costs.

Since pneumatic drives are increasingly used with an integrated guide these days, such ‘guided drives’ also need to meet cleanroom requirements more and more. Conventional bearing systems comprising guide rails and ball bearing slide units are just as suitable as an individual pneumatic drive.

Electric drives in cleanrooms

It is important to mention in this context that electric drives too, like e-cylinders, e-axes and e-handling systems, can be used in cleanrooms without any problems. In many cleanroom applications, pneumatics and electrics complement each other perfectly.
Manufacturers of pneumatic and electric automation components offer an increasing number of products that are qualified for cleanroom applications. Some manufacturers stock a special product range for cleanroom products. Others, including Festo, will specify some of their series products and subject these products to a cleanroom test in order to ascertain their individual suitability. The benefit of the second approach is that they are globally available at short notice, usually at the same low price as a catalogue product.

As they are conventional series components, there are no changes to the level of availability to which customers are accustomed.

With special product ranges, availability at short notice cannot always be guaranteed.

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Figure 7: Qualified series products of Festo AG & Co KG for use in ISO Class 4 to 6

More information on cleanrooms and cleanroom classifications:

[www.festo.de/cleanroom](http://www.festo.de/cleanroom)

Sources:
- ISO 14644 standard
- VDI 2083 directive, sheet 9.1
- Competence Center for Cleanroom Technology Festo Singapore
- Photos: Festo AG & Co. KG

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