

Clean-room technology



(Picture: Rivisa, Switzerland)

What is the purpose of a clean room?

Numerous modern technologies are confronted by increasing demands on the components being clean. The objective of the clean-room technology is to enable the production or entire production sequences under conditions which preclude a harmful influence of contamination. A multitude of reasons exist for this:

- Medical technology frequently relies on moulded articles which are used in a sterile environment. This means that the parts in question must not be infected by cultures or contaminated with particles already on arrival.
- In the case of optical products there is no dust allowed on the surface when the parts are subjected to the coating process, otherwise the layer may come off, refractions can occur at unevennesses or other faults may be evident. Examples of such products are lenses for optical systems or spectacles featuring anti-reflex and anti-scratching layers, or headlight glasses with an anti-scratching layer.
- There is a growing market for products of the micro- and nano-technologies. Special problems must be coped with in

these areas. Contaminations, for example, are usually bigger than the structures on the product. There is a danger of the structures being rendered useless. In micro-systems such as channels and pumps a failure of the system can result from the most minute particles. Just think of the line diameter of a micro-membrane pump ...

What is a clean room?

General

Clean rooms are closed rooms with purified air in which the particle concentration is kept at a specified level. Special guidelines are in place for the room air technology, room furnishings, process equipment, personnel, consumables and the organisation of sequences and procedures.

Categories

The cleanness of the applied air is expressed in categories on the basis of particles existing in a volume to be inspected. A low number of particles means that the moulded products are protected from contamination. The guideline US FED-STD 209E for cleanness categories was officially withdrawn in November

2001 in favour of the international standard ISO 14644.

Contamination

While particles are a form of contamination in a constant quantity, germs build up cultures and are therefore an increasing contamination. Fungi, viruses and bacteria are among the latter group. The European Union has defined provisions for the production of the moulded articles in the EU hygiene zones A–D. A certain clean-room category is required depending on the intended application. Certain products must even be produced in a specified category.

What can Netstal offer its customers?

In principle every Netstal machine can be used in the clean room subject to minor adaptations which concern mainly their handling and suitability for cleaning. By appropriate measures it is possible to produce in clean-room category ISO 6 (US FED-STD 209E = 1000). The most important machine properties for operation in the clean room are the high availability and precision. Since it is known that humans are the biggest source of particle emission, it is of utmost importance that the machines

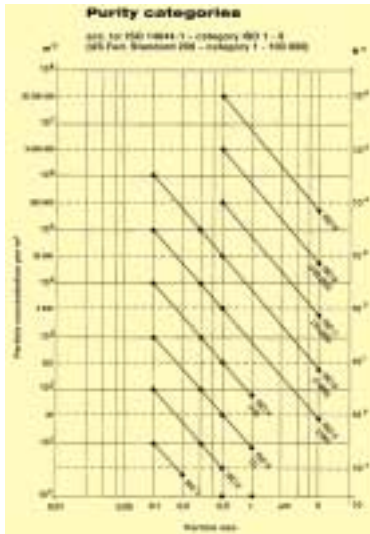
Hygiene zone	A		B		C		D	
Activity	Aseptic production of products which cannot be sterile filtered. Filling of all aseptic products.		Environment of A, transfer into closed product systems of open aseptic products and parts coming into contact with the product.		Filling of products which can be sterilized in the end container, preparation of products which can be sterile filtered, environment of insulators and bottlepack (wish of FDA)		Preparation of products which can be sterilized in the end container in largely closed systems, environment of insulators (EU minimum requirement)	
Particles/m³**	Rest*	Op.	Rest*	Op.	Rest*	Op.	Rest*	Op.
≥ 0.5 micrometers	<3500	<3500	<3500	<350 000	<350 000	<3 500 000	<3 500 000	
≥ 5 micrometers	0	0	0	<2000	<2000	<20 000	<20 000	
Germs/m³	<1	<1	<10	<10	<100	<100	<200	<200

* after clean-up phase of 15 to 20 minutes

** air sampling method



SWISS MADE



Your advantages

- High availability and reliability
- Quality from the first shot onwards
- Mould compartment free of lubricant thanks to seals integrated in mould platens
- Safety cover with open top to allow laminar clean air flow around the mould
- Splinterproof two-component lacquer in high-gloss execution
- Quality plastic panes resistant to cleaning and disinfection agents
- Smooth protective hoses for cables
- Raised base frame facilitating cleaning under the machine
- Closed control cabinet with cooling by heat exchanger
- Documentation in conformity with GMP
- Validation and calibration
- Machine with hoist for clean-room areas without crane
- Machine control with operator identification

require the least possible interventions. Extended maintenance intervals and a good quality of the moulded articles from the first shot onwards are further criteria in the interest of not additionally taxing the air conditioned at considerable expense.

For a clean-room production Netstal offers its injection moulding machines in three variants:

1. The moulding machine is com-

pletely in the clean room and has an open safety cover at the top. This is the simplest variant to produce under clean-room conditions.

2. The machine's mould closing unit is in the clean room, while the plasticizing unit is in the so-called grey room (representing the personnel's working sphere). The actual clean room takes up less space and needs less cooling.

3. The machine is completely in the grey room. A laminar flow box above the mould guarantees that the clean-room conditions are met for both production and transport of the products to the clean room. Less space and cooling are required for the clean room. Access for operation and assembly is much easier in the grey room.

Clean-room category acc. ISO 14644	5	6	7	8
formerly US Federal Standard 209	100	1000	10 000	100 000
Typical applications	CD, DVD			
			Pharma packaging	
	Medical parts			
			Food packaging	
				Parts with contamination problem
Machine-technical solution				Laminar flow box
		Clean-room tent with roof construction		
	Fully encapsulated clean-room cabin			

Your benefit

Motivated by the requirements of customers who are already operating Netstal clean-room equipment in their production plants worldwide, we have accumulated a host of experience in this particular field. This know-how coupled with the high application-technical competence enables Netstal to provide its customers with first-class equipment ready for production.



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