APPROVAL FOR CLEANROOMS

Cleanrooms are areas of production that have very strict requirements on the amount of pollutants, such as such as dust particles, microbes, aerosol particles or chemical fumes. Therefore, there is a controlled level of pollution, which is determined by the number of particles per m^3 and at the same time the maximum particle size.

For the air distribution in the cleanrooms are crucial especially the following parameters:

- Strict limitations on the number of possible particles per m^3 of air.
- It is necessary to maintain a consistent temperature to ensure the stability of the ongoing processes.
- The humidity is controlled as well, to prevent the growth of unwanted microorganisms or electrostatic discharges.
- Airflow, air velocity and volume are designed and maintained to generate a one-directional flow that takes particles away from sensitive areas.
- To eliminate the inflow of unwanted particles through the air distribution are used different filtration that can capture particles of different sizes.

However these parameters are not uniform and can vary depending on the cleanroom class, the industry or the application. Thus, cleanrooms in semiconductor manufacturing, pharmaceutical, medical or aerospace may have completely different requirements.

Specifications of individual cleanrooms:

- **Pharmaceutical industry:** attention is paid to ensure non-contamination of drugs by microorganisms and the homogeneity of drugs in individual batches.
- **Electronics and semiconductor industry:** the presence of unwanted particles would have disastrous consequences - a short circuit.
- **Food processing industry:** the products must be durable and free of any preservatives and must be produced without any dangerous bacteria.

Classification of clean rooms

Cleanrooms are categorised by the level of cleanliness they are able to maintain, primarily by the maximum allowable number of particles per cubic metre of air. The most commonly used classifications are ISO 14644-1 or the European Union Good Manufacturing Practice (EU GMP) for the pharmaceutical industry.

Standard ISO 14644-1

Represents a global standard which assigns a numerical value indicating the maximum acceptable quantity of particles of a certain size per m^3 of air. The lower the ISO class number, the cleaner the environment. For example, ISO Class 1 is the cleanest, with the most stringent particle limits, while ISO Class 9 is the least clean.

CLASS	≥ 0,1 µm	≥ 0,2 µm	≥ 0,3 µm	≥ 0,5 µm	≥ 1 µm	≥ 5 µm
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

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EU Good Manufacturing Practice (EU GMP)

The guidelines provide specific requirements for cleanrooms, specifically for the pharmaceutical industry and the manufacture of sterile products for medical purposes. This classification recognizes two states, rest and operating.

The resting state represents the situation of a space ready for use, which means that all services, such as electricity or air conditioning, are connected and functioning as they should. However, no staff are present and the space is not actively in use.

The operational state is then a situation where everything works the same as in the rest state, however, there is also a defined number of employees who are doing predefined operations.

The separation of these two states is especially significant because the performance and cleanliness of a space can vary depending on whether it is empty or actively operated with the presence of staff.

CLASS	RESTING STATE		OPERATIONAL STATE	
	The maximal amount of dust particles per m^3 of air			
	≥ 0,5 µm	≥ 5 µm	≥ 0,5 µm	≥ 5 µm
A	3.500	< 1	3.500	< 1
B	3.500	< 1	350.000	2.000
C	350.000	2.000	3.500.000	20.000
D	3.500.000	20.000	-	-

A comparison of both standards

For comparison between the two classifications, following table mentions also the „old" US federal classification (FD209E) with classes 1, 10, 100, 1,000, 10,000 and 100,000, since many experts use this classification so far.

The cleanliness classification levels defined by FS209E and ISO 14644-1 are approximately the same, except that the new ISO standard uses a new class designation, a metric measure of air volume and adds three additional classes - two cleaner than Class 10 and one beyond Class 100,000.

STANDARD				
ISO 14644-1	US FEDERAL CLASSIFICATION		EU GMP	
D	METRIC	IMPERIAL	RESTING STATE	OPERATIONAL STATE
1	-	-	-	-
2	-	-	-	-
	M1	-	-	-
3	M1.5	1	-	-
	M2	-	-	-
4	M2.5	10	-	-
	M3	-	-	-
5	M3.5	100	A/B	A
	M4	-	-	-
6	M4.5	1.000	-	-
	M5	-	-	-
7	M5.5	10.000	C	B
	M6	-	-	-
8	M6.5	100.000	D	C
	M7	-	-	-
9	-	-	-	-

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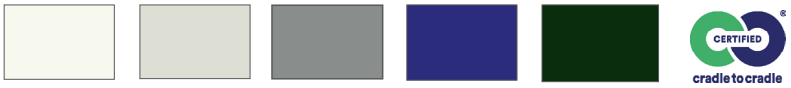
Textile ducts for cleanrooms

For the use of fabric duct in cleanrooms we offer our fabric DFC-HT / B-s1,d0 / Cleanroom Class 4.
This fabric is characterized by the following:

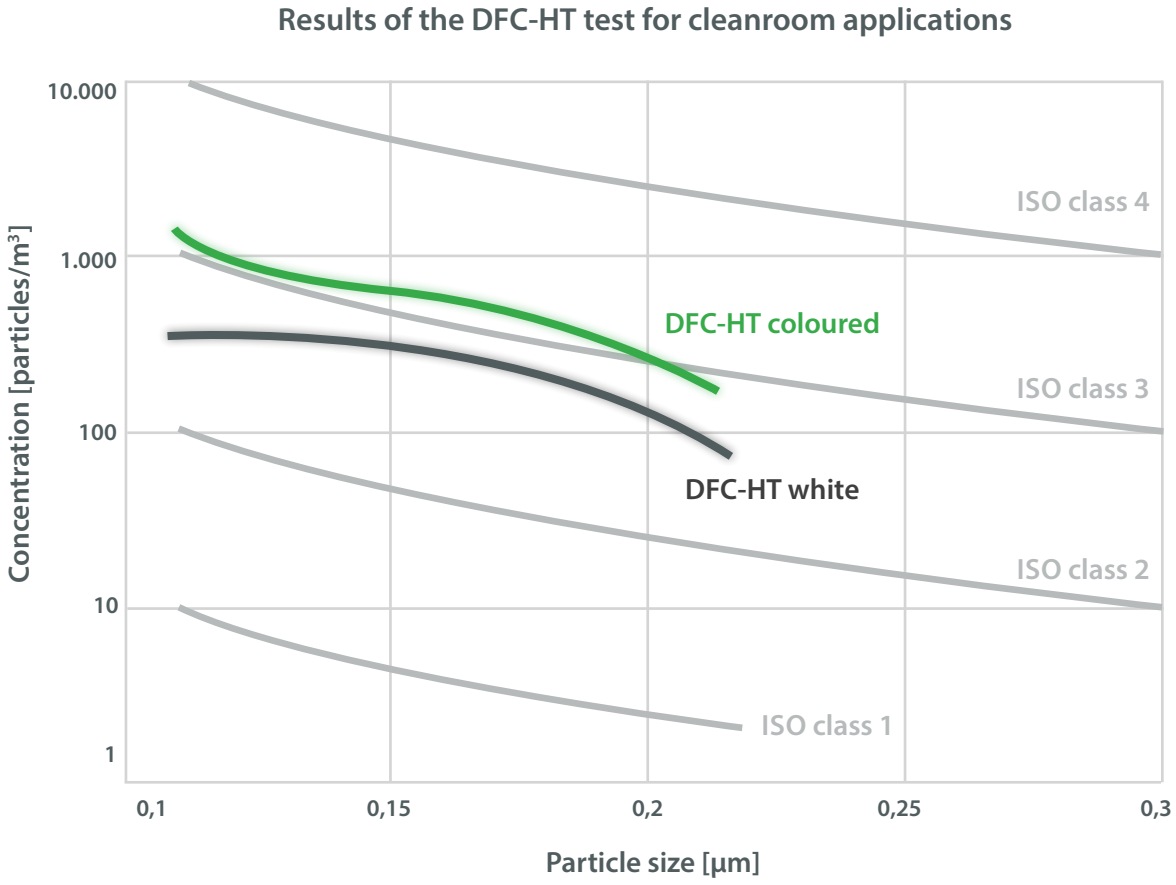
- The filtration of the supply air through the fabric is equivalent to the filtration of a G2 pre-filter according to EN779:2012.
- Certified material for Class 4 cleanrooms according to ISO 14644-1.
- Certified for fire resistance according to EN 13501 B-S1-d0 even without additional surface treatment.
- The material strength is 10-210 N according to EN ISO 13937:2.
- The maximum shrinkage of the material during washing is 0,5 %.
- The standard warranty for material produced in our weaving mill is 10 years.
- 5 different permeabilities to obtain optimal performance of the system according to the given requirements.
- Permeabilities of 20, 85, 325 m3/m2/h and 600 m3/m2/h are available in 3 basic colours (white, light grey and dark blue) and for a permeability of 40 m3/m2/h in 5 colours (white, light grey, dark grey, dark blue and black). For all permeabilities we also offer the option of custom RAL colours.



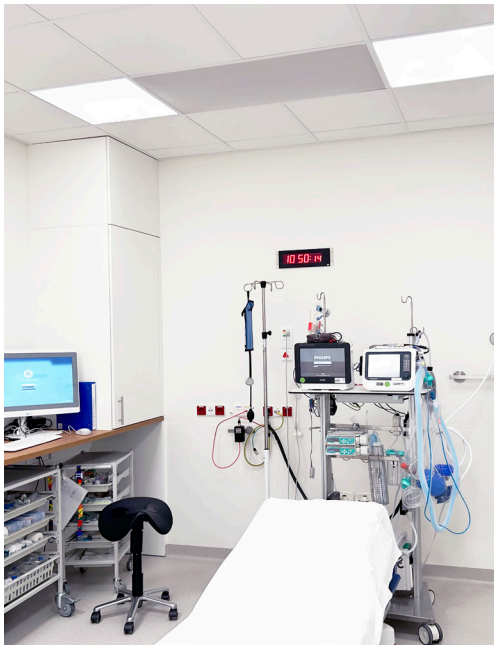
9010 9002 7042 5002 9005

- Possibility of certification according to the Cradle to Cradle standard if other conditions of the certificate are met.

Testing was carried out on specific air pollution with laser aerosol. The result of this testing is shown in the following graph.



Examples of installations in cleanrooms



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