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AIR THE WAY YOU WANT

KE Datasheet
Cleanrooms

A cleanroom is a manufacturing environment that only allows a low level of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapours.

More accurately, a cleanroom has a controlled level of contamination that is specified by the number of particles per m^3 and by the maximum particle size.

In cleanrooms
- the concentration of particles is under control
- the pressure is controlled
- the critical parameters are often monitored
- the critical particles are invisible

White 11-0601-TP | Light Grey 12-4705-TP | Dark Blue 19-3864-TP

Typical cleanroom applications

Pharmaceutical industry
- Medicaments must be free of micro organisms
- Medicaments must be the same from batch to batch

Electronics and semiconductor industry
- Unwanted particles may cause short circuits and catastrophic results

Food industry
- Foodstuffs must have a long shelf life without preservatives and must be produced without any harmful bacteria

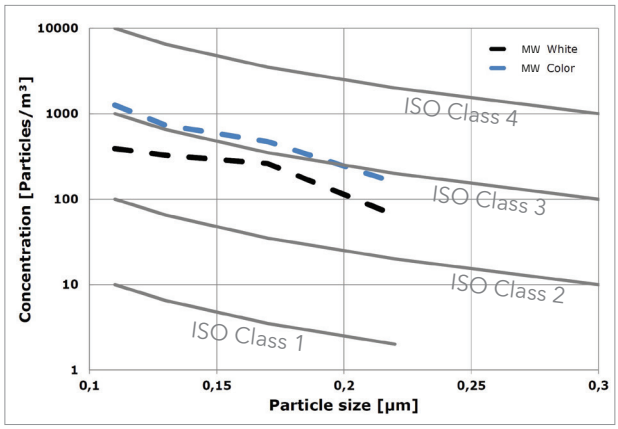

Figure 1: Test results for cleanroom KE Textile materials

Textile ducts for cleanroom applications

KE Fibertec offers 5 different permeabilities of the MultiWeave (MW) material for cleanrooms. All materials are tested for particulate air pollution by means of a laser aerosol spectrometer and have been found applicable for use in ISO class 4 cleanrooms (see figure 1 and overleaf).

KE Fibertec's MultiWeave cleanroom fabrics are available in white, light grey, and dark blue.

Cleanroom classifications

Cleanrooms are classified according to the cleanliness level of the air inside them. The cleanroom class is a standard determined by the contamination control industry and other organizations to provide a qualified and standardized method for measuring how clean the air is in a cleanroom.

Classification of cleanrooms is made on the following basis:

- ISO classification (ISO 14644-1)
- EU GMP classification (pharmaceutical industry)

ISO 14644-1 is the worldwide standard for the classification of cleanrooms. This standard specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones. Table 1 shows the ISO 14644-1 cleanroom classifications.

Table 1: ISO-14644-1 classification

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

The EU GMP (Good Manufacturing Practice) classifications (table 2) are made for pharmaceutical applications for manufacturing of sterile medicinal products. The EU GMP contains requirements for cleanliness in "at rest" state and "in operation" state:

At rest:
All the services are connected, all the equipment is installed and operating to an agreed manner, but no personnel is present.

In operation:
All equipment is installed and is functioning in the defined operating mode, and a specified number of personnel is present, working to an agreed procedure.

Table 2: EU GMP classification

Class	At rest		In operation	
	Maximum number of particles per m^3 room-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	-	-

Table 3: Comparison of classifications

Standard				
ISO 14644-1	American federal	American federal	EU GMP	
	Metric	Imperial	At rest	In operation
1	-	-	-	-
2	-	-	-	-
	M1	-	-	-
3	M1.5	1	-	-
	M2	-	-	-
4	M2.5	10	-	-
	M3	-	-	-
5	M3.5	100	A/B	A
	M4	-	-	-
6	M4.5	1000	-	-
	M5	-	-	-
7	M5.5	10.000	C	B
	M6	-	-	-
8	M6.5	100.000	D	C
	M7	-	-	-
9	-	-	-	-

To compare the two classifications, see table 3. Also the "old" American federal classification (FD209E) with class 1, 10, 100, 1.000, 10.000 and 100.000 is shown, as many consultants still use these terms.

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

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