



Table of contents

1	Flex	xibowl® option for Clean Room	3
1.	.1	Description	3
1.	.2	Parts list	4
1.	.3	Use	5
1.	.4	Installation and Maintenance	5

1 Flexibowl® option for Clean Room

1.1 Description

The Cleanroom option can be used with **Flexibowl**[®] 500/650/800 models with Clockwise (C) and Counterclockwise (CC) configurations and is designed to make the device compatible for use in Cleanroom **class ISO 5** in accordance with **ISO 14644-1**:

ISO Class number (N)	Maximum allowable concentrations (particles/m³) for particles equal to and greater than the considered sizes, shown below ^a						
	0,1 μm	0,2 μm	0,3 μm	0,5 μm	1 µm	5 µm	
1	<i>10</i> b	d	d	d	d	е	
2	100	<i>24</i> b	<i>10</i> b	d	d	e	
3	1 000	237	102	35 ^b	d	е	
4	10 000	2 370	1 020	352	83 ^b	е	
5	100 000	23 700	10 200	3 520	832	d, e, f	
6	1 000 000	237 000	102 000	35 200	8 320	293	
7	с	с	с	352 000	83 200	2 930	
8	с	с	с	3 520 000	832 000	29 300	
9g	с	с	с	35 200 000	8 320 000	293 000	

Table 1 — ISO Classes of air cleanliness by particle concentration

a All concentrations in the table are cumulative, e.g. for ISO Class 5, the 10 200 particles shown at 0,3 μm include all particles equal to and greater than this size.

^b These concentrations will lead to large air sample volumes for classification. Sequential sampling procedure may be applied; see <u>Annex D</u>.

c Concentration limits are not applicable in this region of the table due to very high particle concentration.

d Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

e Sample collection limitations for both particles in low concentrations and sizes greater than 1 μm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.

^f In order to specify this particle size in association with ISO Class 5, the macroparticle descriptor M may be adapted and used in conjunction with at least one other particle size. (See <u>C.7.</u>)

This class is only applicable for the in-operation state.

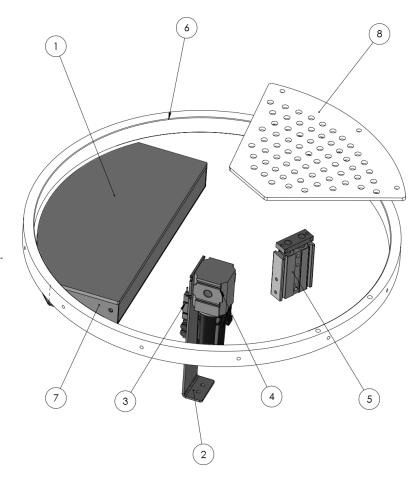
Class ISO 5 according to ISO 14644-1 is equivalent to class 100 according to FED FS209:

ISO 14644-1	FS 209				
Classes					
ISO 3	1				
ISO 4	10				
ISO 5	100				
ISO 6	1,000				
ISO 7	10,000				
ISO 8	100,000				

The materials used in the optional accessory, such as stainless steel, glass and natural polycarbonate, have suitable properties for controlled atmospheres, even in the presence of friction and abrasion.

1.2 Parts list

The Cleanroom parts list consists of:



Position	Part no.	Description	Quantity
1	PD002787	Glass window	1
2	PD002516	L-shaped bracket	1
3	CM000961	Cleanroom solenoid valve	1
4	CM000962	Cleanroom filter	1
5	CM000993	Pneumatic dual rod cylinder for Cleanroom	1
6	PD001072	Upper Guide Ring	1
7	PD002788	Backlight support	1
8	PD002789	Guard	1
	СМ000994	Silencer filter for sterile chamber to be installed on the solenoid valve, pos.3	2

The guard (pos.8) is perforated to facilitate the laminar flow of air from top to bottom, which keeps the airborne concentration of particles low.

The belt is not included in the Cleanroom option and a choice of belt with FDA features is recommended.

The cleanroom kit is compatible with all types of FDA belts in the ARS catalogue: <u>https://www.flexibowl.it/download/appendice-a-flexibowl-rotary-discs</u>

1.3 Use

The **Flexibowl**[®] Cleanroom kit does not alter the device's operation and control. Therefore, please refer to the standard product ARS technical documentation available at: <u>https://www.flexibowl.it/</u>.



1.4 Installation and Maintenance

The **Flexibowl**[®] Cleanroom kit option does not alter the device's installation and maintenance requirements. Therefore, please refer to the standard product ARS technical documentation available at: https://www.flexibowl.it/.

Additional caution is recommended when removing and handling the glass window, position 1 in the list in paragraph 1.2, due to the material's fragility.



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