uvmedico

B4 Health

UV222 Booth

Cleanrooms

UV222 for the disinfection of classified areas

Enter your cleanroom clean.

WHAT IS A CLEANROOM?

A cleanroom is a space designed to maintain a very low concentration of airborne particulates. It is isolated, actively cleansed and monitored for any potential contamination.

Clean-controlled environments are used to control and limit microbiological contamination where there is a risk to product quality, patient or consumer. They are used in many industries, being particularly stringent the requirements in the pharmaceutical industry.

Whether manufacturing pharmaceuticals, working with nanotechnologies or researching biological specimens, even the smallest particles in the air can cause devastating results requiring expensive downtime and cleanup procedures.

CLASSIFICATION: *AIRBORNE PARTICLE CONTAMINATION*

Cleanrooms are classified according to the number and size of airborne particles per volume of air. There are several standards proposing cleanroom classifications, but the most used are:

- EudraLex Vol. 4, **EU GMP,** Annex 1: Manufacture of Sterile Medicinal Products.
- **ISO 14644**, Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration.

EUROPEAN GMP CLASSIFICATION

EU GMP Grade	Maximum permitted number of particles per m^3 equal to or greater than the tabulated size				Description
	At rest		In operation		
	0.5 µm	5.0 µm	0.5 µm	5.0 µm	
A	3 520	20	3 520	20	The local zone for high risk operations, e.g. filling zone, open ampoules and vials, making aseptic connections.
B	3 520	29	352 000	2 900	For aseptic preparation and filling, this is the background environment for the grade A zone.
C	352 000	2 900	3 520 000	29 000	Clean areas for carrying out less critical stages in the manufacture of sterile products.
D	3 520 000	29 000	Not defined	Not defined	

CLASSIFICATION: *AIRBORNE PARTICLE CONTAMINATION*

ISO 14644, Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration.

ISO 14644-1	Maximum permitted number of particles per m^3 equal to or greater than the tabulated size						Description
Class number	≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ 0.5 µm	≥ 1.0 µm	≥ 5.0 µm	
1	10	-	-	-	-	-	-
2	100	24	10	-	-	-	-
3	1 000	237	102	35	-	-	-
4	10 000	2 370	1 020	352	83	-	-
5	1 00 000	23 700	10 200	3 520	832	-	EU GMP grade A/B
6	1 000 000	237 000	102 000	35 200	8 320	293	-
7	-	-	-	352 000	83 200	2 930	EU GMP grade C (at rest)
8	-	-	-	3 520 000	832 000	29 300	EU GMP grade C (in operation) and grade D (at rest)
9	-	-	-	35 200 000	8 320 000	293 000	Room air

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CLASSIFICATION: *MICROBIAL CONTAMINATION*

Cleanrooms are also classified according to the microbial contamination limits. The regulations establishing the mentioned limits are:

- EudraLex Vol. 4, **EU GMP,** Annex 1: Manufacture of Sterile Medicinal Products.
- **EN 17141**, Cleanrooms and associated controlled environments – Biocontamination control.

EU GMP Grade	Recommended limits for microbial contamination				EN 17141 Classification
	air sample cfu/m3	settle plates (diameter 90 mm) cfu/4 hours	Contact plates (diameter 55 mm) cfu/4 hours	glove print 5 fingers cfu/glove	
A	<1	<1	<1	<1	**1**
B	10	5	5	5	**2**
C	100	50	25	-	**3**
D	200	100	50	-	**4**

CONTAMINATION SOURCES

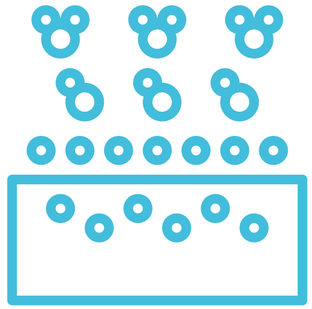
STAFF

The most significant source of contamination (about 80% cases).

AIR

Dust and aerosols in the air represent the second main source of cleanroom contamination.

SURFACES



Most organisms on surfaces will be from the air, or they will originate from items introduced into the cleanroom.

CURRENT CONTAMINATION CONTROL MEASURES

STAFF

PROTECTIVE EQUIPMENT

PERSONNEL TRAINING

SAFE CHANGING ROOMS

HAND SANITIZERS

AIR

FILTRATION

DILUTION

AIR MOVEMENT

DIRECTIONAL AIR FLOW

SURFACES

CHEMICAL CLEANING:

Disinfectants
Antiseptics
Sterilizing agents

FAR UV-C CAN IMPROVE CLEANROOM HYGIENE

A person entering controlled areas carries foreign particles, being a potential source of contamination. The same is the case for raw materials and tools.

UV Medico has developed an adapted solution for the pharmaceutical industry using UV222 technology: the UV222 Booth.

The UV222 Booth can help maintain the established limits for microbial contamination, by disinfecting gowned personnel right at the entrance of manufacturing areas.

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ENTER YOUR CLEANROOM CLEAN

Introducing UV222 Booth, the only available solution that keeps workers clean upon entering the cleanroom.

The UV222 Booth has been designed specifically for minimising pathogen loads from worker uniforms and gear before entering sterile environments like cleanrooms and medical facilities.

Using the versatile UV222 patented filtered Far UV-C which has been proven to be safe for use in occupied spaces, the UV222 Booth offers disinfection in under 30 seconds.

UV222 Booth uses an advance touchless operation interface with built-in safety parameters that offer a complete solution for areas where disinfection was not fully achievable up until today.

- Care222® patented filtered Far UV-C
- 30 second cycle (programmable)
- Touchless ON/OFF operation
- Instruction interface for maximum results
- High efficacy against bacteria, spores, fungi
- Low impact on gloves, uniforms and gear
- Built-in on/off safety features
- Easy installation and use
- Made with high grade stainless steel

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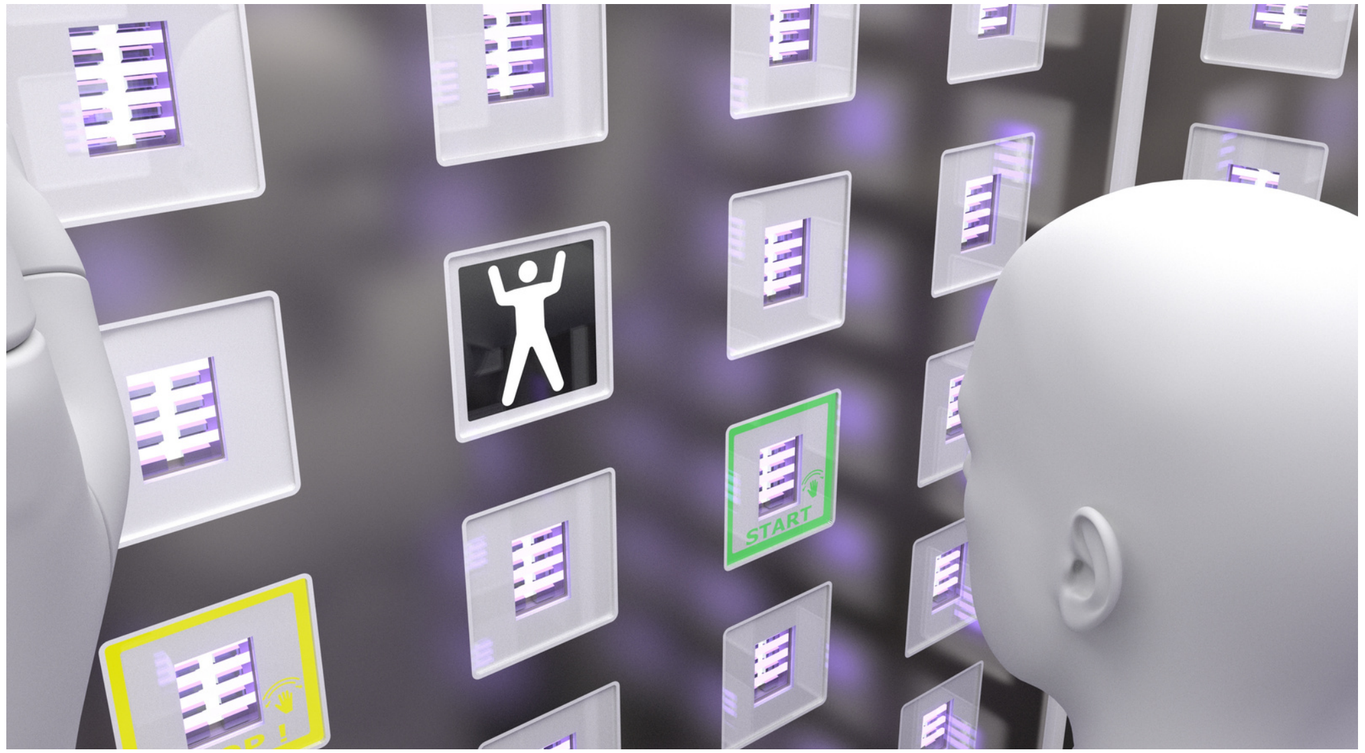
UV222 Booth

Touchless operation interface.

Operation status indication.



Audio and visual indication of disinfection cycle.

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UV222 BOOTH EFFICACY

Microorganism	Type	UV dose for 90% reduction (mJ/cm²)*	Time for disinfection in UV222 Booth (sec.)**	Microorganism	Type	UV dose for 90% reduction (mJ/cm²)*	Time for disinfection in UV222 Booth (sec.)**
Arthrobacter nicotinovorans	Bacteria	5.97	15.37	Candida albicans	Fungi	9,82	25.28
Bacillis subtilis	Bacteria	4.09	10.53	Penicillium expansum spores	Fungi	13,82	35,57
Clostridium sporogenes	Bacteria	2.87	7.39	Saccharomyces cerevisiae	Fungi	12,77	32,87
Enterococcus faecalis	Bacteria	7.59	19.54	Bacillus subtilis spores	Spores	6.34	16,32
Escherichia coli	Bacteria	2.10	5.41	Clostridioides difficile spores	Spores	13.23	34,05
Listeria monocytogenes	Bacteria	3.58	9.21	Adenovirus	Virus	5.09	13,10
Pseudomonas aeruginosa	Bacteria	1.98	5.10	Human coronavirus	Virus	0.48	1,24
Salmonella Typhimurium	Bacteria	1.97	5.07	Influenza virus	Virus	1.28	3,29
Staphylococcus aureus	Bacteria	3.24	8.34	Rotavirus	Virus	4.55	11,71
Streptococcus pyogenes	Bacteria	20.91	53.82	SARS-Cov-2	Virus	1.2	3,09
Yersinia enterocolytica	Bacteria	2.2	5.66	Vaccinia virus	Virus	6.53	16,81

** Time of disinfection in the UV222 Booth has been calculated taking as reference:

- Nr. of light sources: **121**.
- Average irradiance at chest level: **388.5 µW/cm²**.

*Hessling M, Haag R, Sieber N, Vatter P. The impact of far-UVC radiation (200-230 nm) on pathogens, cells, skin, and eyes - a collection and analysis of a hundred years of data. GMS Hyg Infect Control. 2021 Feb 16;16:Doc07. doi: 10.3205/dgkh000378. PMID: 33643774; PMCID: PMC7894148.

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IN COMPLIANCE WITH:

- ROHS Directive 2011/65/EU
- and amendments
- EMC Directive 2014/30/EU
- Machinery Directive 2006/42/EC
- ISO 15858 UV-C Devices – Safety information – permissible human exposure.*

*In agreement with article 5.3 of ISO 15858; personal protective equipment according to the product manual must be used by the operator inside the active UV Booth since instantaneous irradiance exceed the UVC exposure for unprotected skin and eyes.

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