vileda PROFESSIONAL

Three Levels of Clean

Achieve a next level clean for your facility.

NEXT LEVEL CLEAN

a brand of FREUDENBERG

The essence of 70yrs forward thinking:

NEXT LEVEL CLEAN

Everything we do grows from a constant dialogue with our customers. This made us a world leader in innovative cleaning solutions for controlled environments. We provide a complete contamination control concept including planning, trial programs, training and after sales care.

We believe in making people work smarter, not harder.
That is why we focus on ergonomics, performance and design at every stage of the R&D phase, while using unique and patented technologies. All that to help you realise a higher standard, a **NEXT LEVEL CLEAN**, sustainably!

Maximum facility contamination control

In controlled environments, maintaining high standards of contamination control is crucial to ensure the quality, safety, and efficacy of products, particularly in industries such as pharmaceuticals, biotechnology, and microelectronics.

Unchecked contamination risks can lead to product recalls, financial losses, and severe health risks. Your facility is divided into three critical areas were specific activities take place. There are three key considerations to keep top of mind when developing your contamination control SOP's.

We believe in one simple principle "to deliver your facility a Next Level Clean", with cleaning systems that cover all controlled areas in the production plant. To do this successfully, a total contamination control approach must be applied. All surfaces, all units, all areas must be addressed in your specific cleaning SOP's.

A robust and rigorous contamination control plan in your manufacturing space ensures product quality, regulatory compliance, patient safety, and operational efficiency.

Maintaining high standards of contamination control in the cleanroom, the personnel / gowning room, and the controlled environment around the manufacturing area is critical.

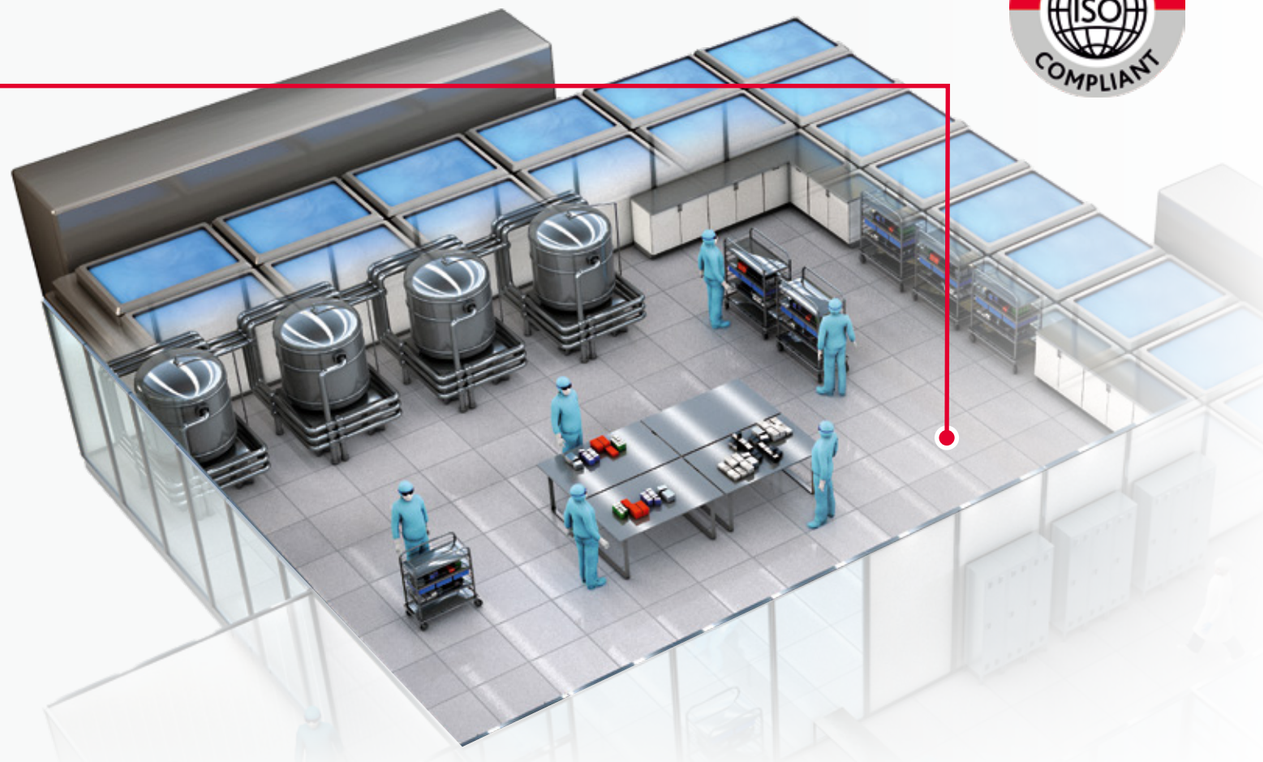
Each critical area in your facility plays a vital role in creating a comprehensive contamination control strategy that safeguards the integrity of the products and the health of your end users.

Area 1

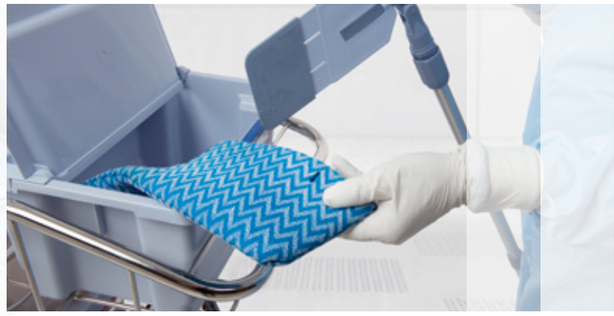
1 THE CLEANROOM

Production area. Validated and contamination controlled environment - air, surfaces and personnel.

- **What type of contamination do you need to control? Spills, particulates or even visible debris?**
- **Are you reaching your contamination goals? CFU's, particle counts, etc?**
- **Do you have external validation material on all your cleaning utensils? Including particle reports for mops?**
- **Are your cleaning textiles (mops/wipes) collecting/ removing contamination from critical surfaces?**
- **Can you control contamination between/within the cleanroom? How often do your operators change cleaning solutions and mops?**
- **Is total cost-in-use of your cleaning program an area where you would like to improve?**
- **Are your staff annually educated/trained in how to execute the cleaning method?**



ISO 4-6 ISO COMPLIANT

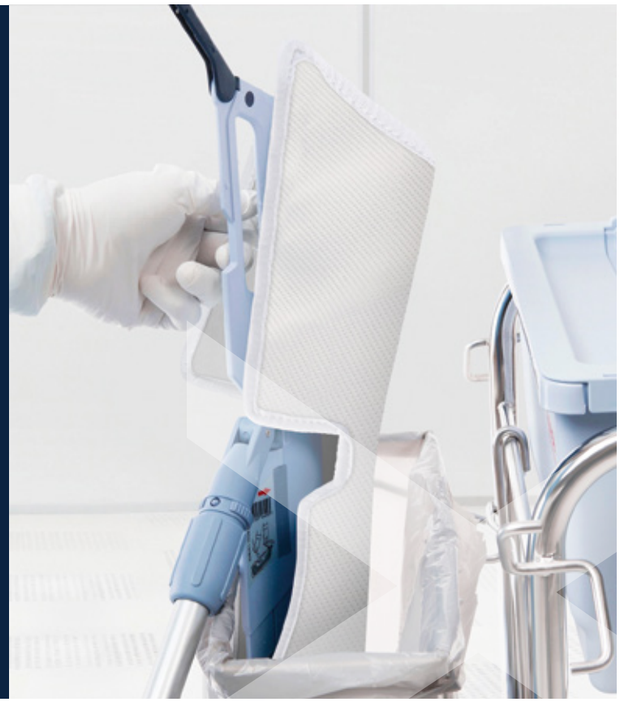


Pre-prepared System:

- CE MicroControl/MicroControl 2
- CE MicronSwep Single/Duo (laundry partners)
- CE MicronSwep Mitt (laundry partners)
- CE EvoControl 400 Sterile
- CE MicroIntensive Duo
- CE Duo CleanTech
- CE Pre-prepared Trolley
- CE Compact Trolley

Bucket System:

- CE MicroControl/MicroControl 2 with Duo-Press
- CE Roll-O-Matic® System
- CE Duo CleanTech
- CE EvoControl 400 Sterile
- CE Bucket Trolley



KEY ACTIVITIES:

- **Manufacturing and Assembly:** Your cleanrooms are where critical manufacturing and product assembly processes occur. These processes require an ultra-clean environment to prevent any contamination that could compromise your product's integrity.
- **Quality Control and Testing:** In-process testing and rigorous quality control checks are performed here to ensure that your products meet the required standards.
- **Packaging:** Final packaging of products is often also conducted in cleanrooms to prevent any contamination before the product is sealed for dispatch.

IMPORTANCE OF HIGH STANDARDS:

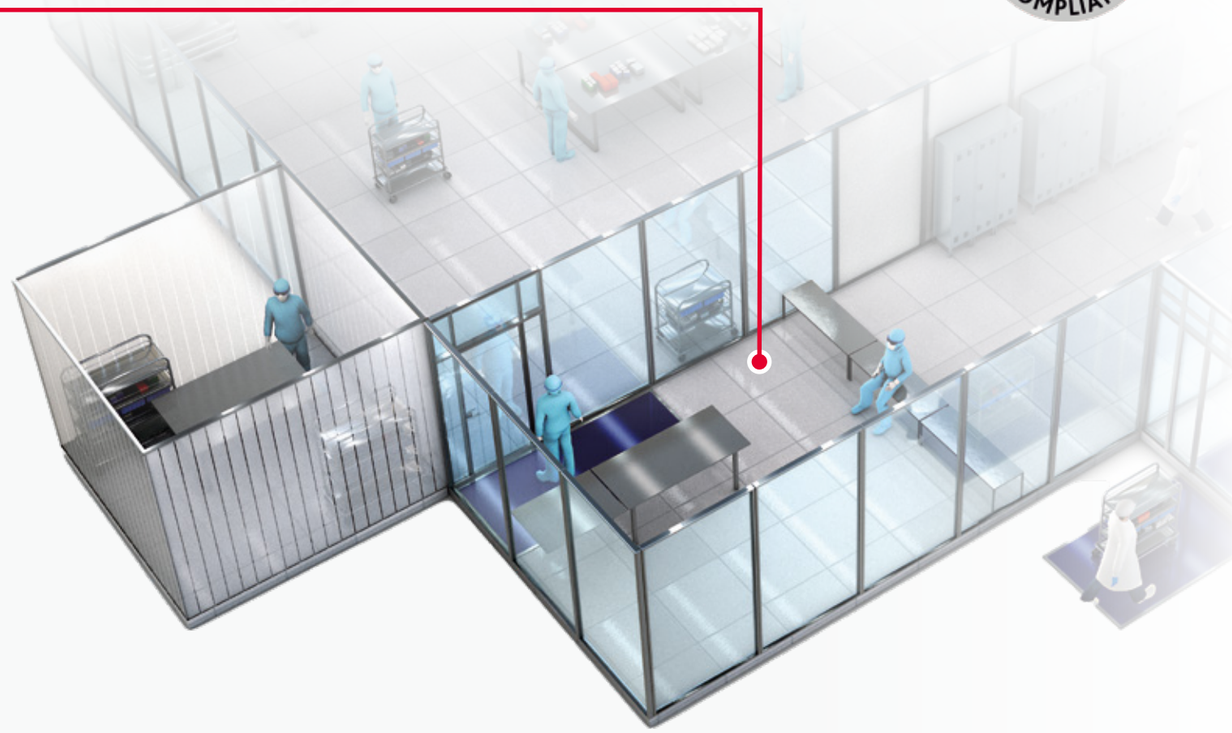
- **Product Integrity:** Even the smallest particles (microns in size) can cause defects in microelectronics or compromise the sterility of pharmaceutical products. High standards of contamination control risk assessment ensure that your products are free from contaminants.
- **Compliance with Regulations:** Industries such as pharmaceuticals are heavily regulated. Adhering to contamination control standards is essential for regulatory compliance, avoiding penalties, and ensuring market access.
- **Patient Safety:** In pharmaceutical and biotechnology industries, contaminated products can have fatal health consequences for patients. Maintaining an ultra-clean environment through detailed SOP's is essential to prevent contamination and ensure patient safety.
- **Yield and Efficiency:** Contamination can lead to production issue and batch failures, which can be costly to your business. Maintaining high standards of contamination control improves your yield KPI's and supports operational efficiency.

Area 2

2 THE PERSONNEL ENTRANCE/ GOWNING ROOM

The personnel entrance and gowning room are designed to eliminate cleanroom operatives as potential sources of contamination before entering the production area. Some aspects of cleaning logistics to consider.

- **Can you easily carry cleaning solutions in and out of the gowning area?**
- **Do you have space to fill buckets?**
- **Can you bring in cleaning trollies and is there enough space?**
- **Can you reach hard to clean areas like underneath equipment?**



ISO 6-8 COMPLIANT

Pre-prepared System:

- CE MicroControl/MicroControl 2
- CE MicronSwep Single/Duo (laundry partners)
- CE MicronSwep Mitt (laundry partners)
- CE EvoControl 400 Sterile
- CE NanoTech Micro
- CE MicroIntensive Duo
- CE Duo CleanTech
- CE Pre-prepared Trolley
- CE Compact Trolley
- SWEP Duo System

Bucket System:

- CE Roll-O-Matic® System
- CE Duo CleanTech with Duo Press
- CE EvoControl 400 Sterile
- CE NanoTech Micro
- CE UltraSpeed Pro System
- CE Bucket Trolley

KEY ACTIVITIES:

- **Gowning and De-gowning:** This is where your contamination control operatives change into specialized cleanroom attire, including coveralls, gloves, masks, and footwear, to prevent contaminants from entering the cleanroom.
- **Personal Hygiene Practices:** Handwashing and sanitization procedures should be strictly implemented and followed here to minimize the risk of cross contamination from personnel.

IMPORTANCE OF HIGH STANDARDS:

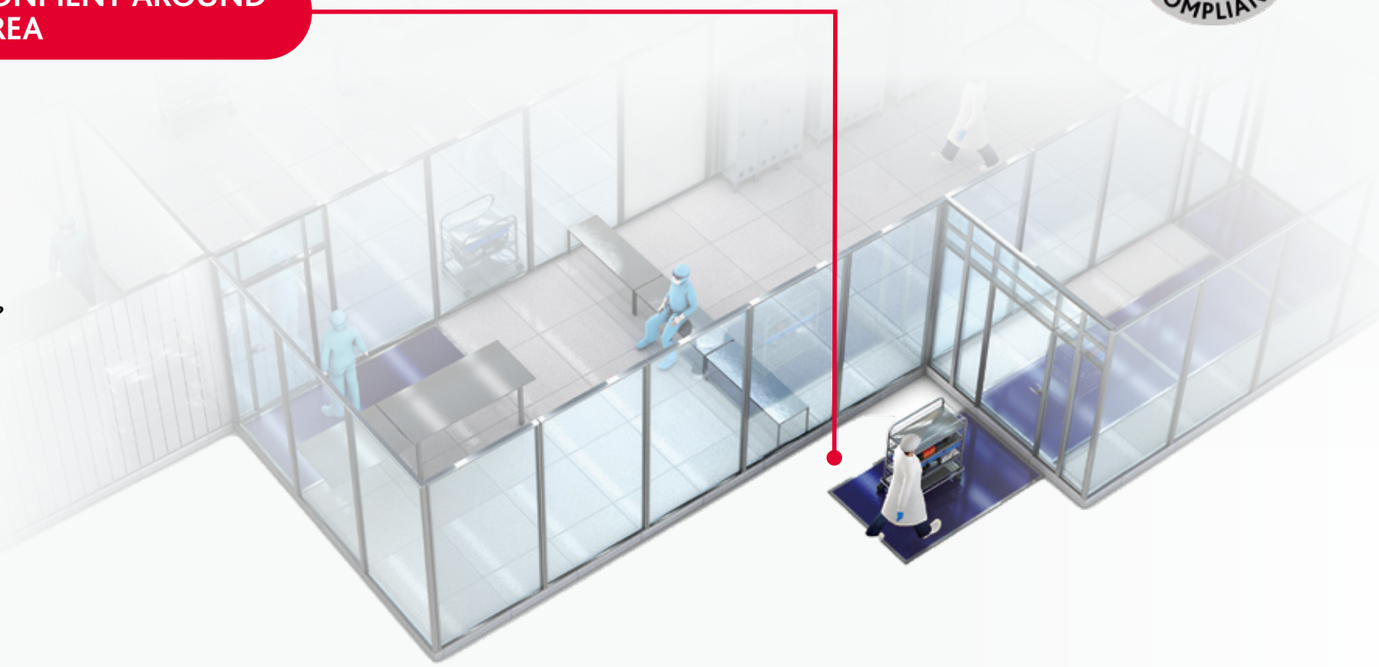
- **Barrier to Contaminants:** The gowning process creates a barrier between the cleanroom environment and potential contaminants carried by personnel, such as sebum, skin flakes, hair, and other harmful particulates.
- **Minimizing Human Contamination:** Humans are the largest source of contamination in controlled environments, rigorous gowning procedures and hygiene SOP practices are essential to reduce this risk in your facility.
- **Training and Compliance:** Ensuring that personnel are properly trained in contamination control protocols is business critical for your facility. High standards ensure that gowning procedures are followed correctly and consistently to minimise the risk of cross contamination.

Area 3

3 THE CONTROLLED ENVIRONMENT AROUND THE MANUFACTURING AREA

Controlled Environment areas including the entrance zone. Surrounding environments impact the cleanliness of the cleanroom – regulated surroundings with established cleaning protocols can prevent up to 80% of contaminants entering the cleanroom.

- **Have you validated your current cleaning system to act as a barrier for your cleanroom?**
- **Are you able to clean with the same method/ tools within other executions, allowing ease of use for the operators? Do you enjoy the benefits of a 'one facility', 'one system' scenario?**
- **Do you know your cleaning cost per m² for this area?**



ISO 8-9 ISO COMPLIANT

Pre-prepared System:

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- CE MicronSwep Single/Duo (laundry partners)
- CE MicronSwep Mitt (laundry partners)
- CE EvoControl 400 Sterile
- CE MicroIntensive Duo
- CE Duo CleanTech
- CE Pre-prepared Trolley
- CE Compact Trolley
- SWEP Duo System

Bucket System:

- CE Roll-O-Matic® System
- CE Duo CleanTech with Duo Press
- CE EvoControl 400 Sterile
- CE UltraSpeed Pro System
- CE Bucket Trolley

KEY ACTIVITIES:

- **Monitoring and Maintenance:** Regular monitoring of environmental conditions, including air quality, temperature, and humidity, is conducted to maintain the required standards your facility requires.
- **Cleaning and Disinfection:** Routine and thorough cleaning and disinfection of surfaces, equipment and air handling systems are performed here to prevent contamination entering the facility.
- **Materials Handling:** Raw materials and components are stored and handled in controlled conditions to prevent cross contamination before they enter the cleanroom.

IMPORTANCE OF HIGH STANDARDS:

- **Environmental Control:** Contaminants can easily enter the cleanroom from adjacent areas if not properly controlled. High standards in the surrounding environment helps to create a buffer zone, reducing the risk of cross contamination.
- **Preventing Cross-Contamination:** Rigorous and robust SOP's, procedures and controls in the surrounding environment help to prevent cross-contamination between different areas, especially when different products or processes are handled near critical environments.
- **Supporting Cleanroom Conditions:** The controlled environment around the cleanroom supports and enhances the cleanliness and control measures within the cleanroom, ensuring an overall contamination-free manufacturing process for your facility.
- **Compliance and Safety:** Adhering to high contamination control standards in all areas, not just the cleanroom, is essential for meeting regulatory requirements and ensuring the safety and efficacy of the final product.

Discover more at
ce.vileda-professional.com

NEXT LEVEL CLEAN

Vileda Professional – a part of the Freudenberg Group

Vileda Professional provides innovative cleaning solutions and systems for professional users in various application areas, such as General Building, Healthcare, HoReCa and Controlled Environment. With sales offices in all major European countries, in North America and Asia – and with a wide net of representatives – we are well located around the world. Vileda Professional belongs to the Freudenberg Group – a diversified family-run global company, headquartered in Germany.

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