



# Micronclean Compliance 100<sup>®</sup> GMP Cleaning Solutions

Total Cleaning Solutions from Micronclean

 micronclean

» Introduction to Micronclean

Micronclean have offered a specialist ISO Class 4/GMP Grade B cleanroom garment service to manufacturing pharmacies and industrial compounders since 1982







*Above: Unique to Micronclean: the Louth RFID, fully automated garment sortation area. Where, thanks to our Protrack software, every garment contract can be arranged into the order or type the customer requires.*

The provision of sterile and non-sterile garments is, of course, both GMP quality driven and a highly detailed activity. This, linked to strong 'point of use' logistics involvement and flexibility to cope with the fluctuations of patient drug production, has led to Micronclean becoming market leader in this field.

**2005** the first Compliance 100® product was developed, 'The Cleanroom Mopping System'.

**2006** saw the second member of the Compliance 100® product family launched - the GMP cleanroom designed wipe range.

**2007** brought the development of a range of sterile syringe packs and associated sterile devices designed for pharmacy and compounding use. Micronclean attained ISO 13485.

**2010** Micronclean launch a specialised sterile alcohol trigger spray to assist users with the cost issues associated with 'spray and wipe' processes adding new product features and benefits, but above all, exceeding compliance requirements.

Micronclean have a dedicated online website for a safe and convenient way to order and schedule consumables, which may then be delivered free of charge on our own extensive fleet of vehicles.





» New in-house designed Mopping System

## Micronclean's Compliance 100<sup>®</sup> Large Scale Mopping System

Building on Micronclean's extensive knowledge and experience with the Compliance 100<sup>®</sup> cleanroom microfibre mopping system.



Cleaning just  
became even  
easier!

» Innovative and bespoke design

The compact mopping system developed and patented by Micronclean some 7 years ago was designed primarily for smaller scale cleanroom applications (< 200M<sup>2</sup> floor area) and is now widely validated and adopted.

The decontamination of larger scale cleanrooms has the same quality requirements, but requires surface areas well beyond 200M<sup>2</sup> to be dealt with via one system.

The heart of the system is the patented mop pouch dispenser which is engineered into a trolley capable of carrying enough mops (and room for soiled mops) for 200M<sup>2</sup> up to 1600M<sup>2</sup> if required. The system is available with a rotational pair of disinfectants already impregnated in the mops or a dry version.

By a process of evolution the original compact system has been safely scaled up to provide a cost effective, bucket-less approach to cleaning and disinfecting large areas.



Bare trolley



Sprays and wipes storage area

Sprays and wipes storage area

Soiled mop collector

Mop handle storage grip

Cleanroom compatible wheels



## » The Compliance 100® Large Scale Mopping System

# How it works

Packs of mops are delivered weekly to customers in packs of 5, 10, 15 or 20, cleanroom decontaminated and impregnated with Compliance 100® rotational disinfectants and gamma sterilised. A dry version is also available.

Remove the outer bag and insert the mop pack into the dispenser attached to the trolley.

Using the system's cleanroom cutter, open the mop bag.



Stage 1

Each mop can process an average of 20M<sup>2</sup> of cleanroom surface.



Stage 2



Stage 3

Micronclean pick up soiled mops and provide next batch of clean impregnated mops. The cycle then repeats.

Lastly, seal the plastic waste bag and remove from trolley.

Once all the soiled mops have been placed into the net bag on the collector, close using the draw string and allow the closed net bag to sit inside the waste plastic bag already surrounding it.



Stage 12



Stage 11



Stage 10

The now opened bag is then stretched over the special spring action arms. This action ensures unimpeded access to the 'stack' of mops.

The stainless steel mop head frame is hinged and by un-clipping this hinge, the mop frame can be lowered into the open bag and engaged into the mop end pockets.

Once the mop frame is engaged, a light push locks the hinge and the mop and frame are now connected and ready to use without having to touch the mop with gloved hands.



Once a mop is used, a single click on the mop frame over soiled collector releases the used mop into the provided net bag. Process starts again.

Floor mopping is best approached with the mop head adjusted to move in two planes, so an overlapping sinusoidal action is made.

Each mop within the pack will effectively cover 20M<sup>2</sup> depending on levels of contamination. Wall and ceiling use is easiest with mop head set to move in one plane only.



## » The Compliance 100® Large Scale Mopping System

# Mop Processing

The ISO Class 4 cleanroom handles the incoming mops via a specialised mop laundry cycle. The barrier washing machines are SCADA monitored and logged for critical parameters: thermal disinfection, conductivity and duration, to ensure traceable processing data for the individually barcoded mops in each net bag.

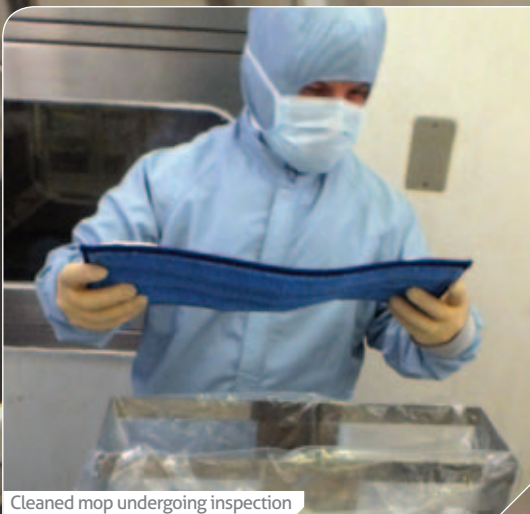
Each net bag exclusively contains a customer's own soiled mops, consequently programmes can be developed for difficult to clean materials etc. Of key importance is the adherence to returning all mops via the net bag system.

100% inspection and traceability, essential for GMP compliance and cleaning performance consistency.

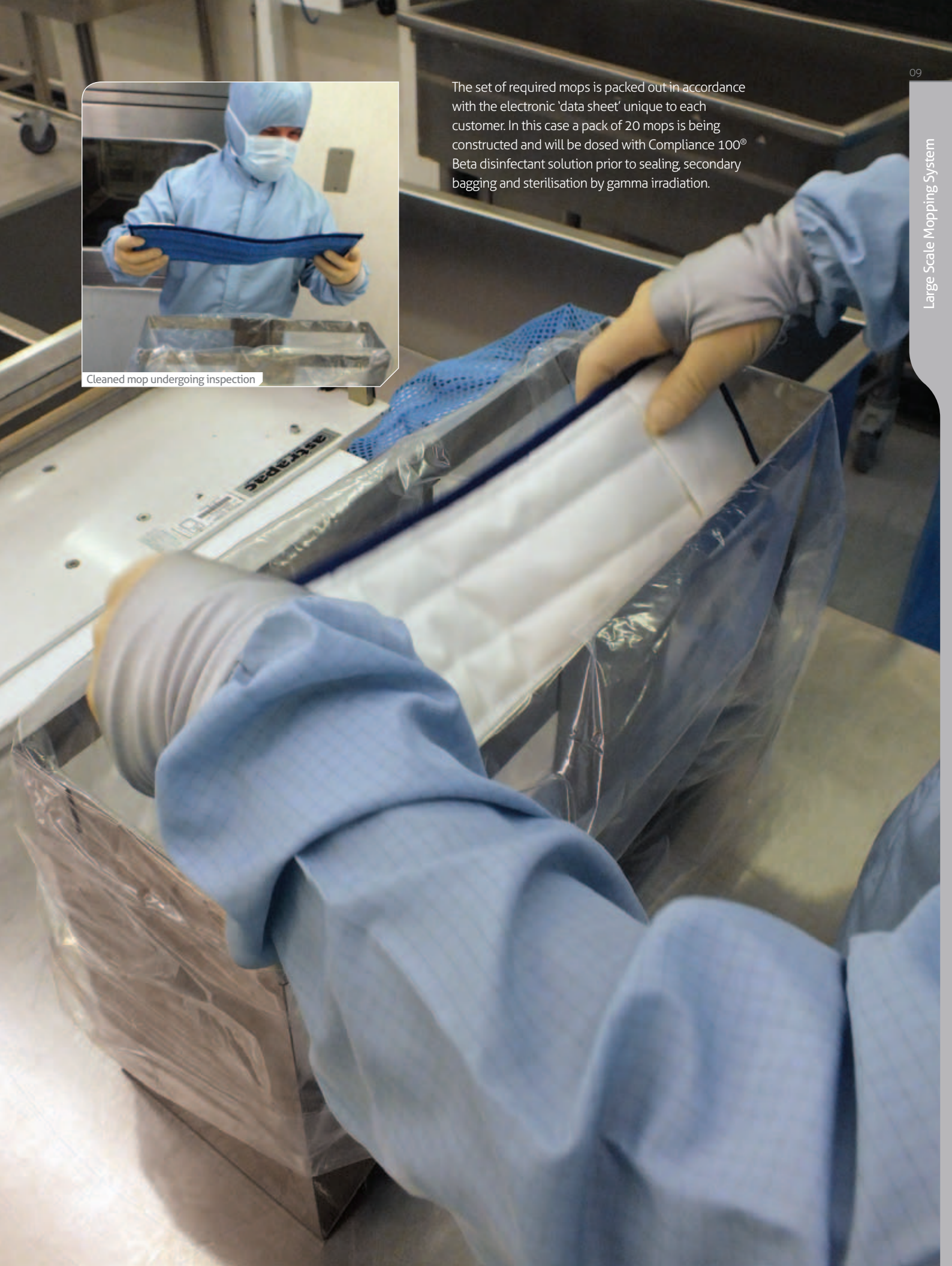




The set of required mops is packed out in accordance with the electronic 'data sheet' unique to each customer. In this case a pack of 20 mops is being constructed and will be dosed with Compliance 100® Beta disinfectant solution prior to sealing, secondary bagging and sterilisation by gamma irradiation.

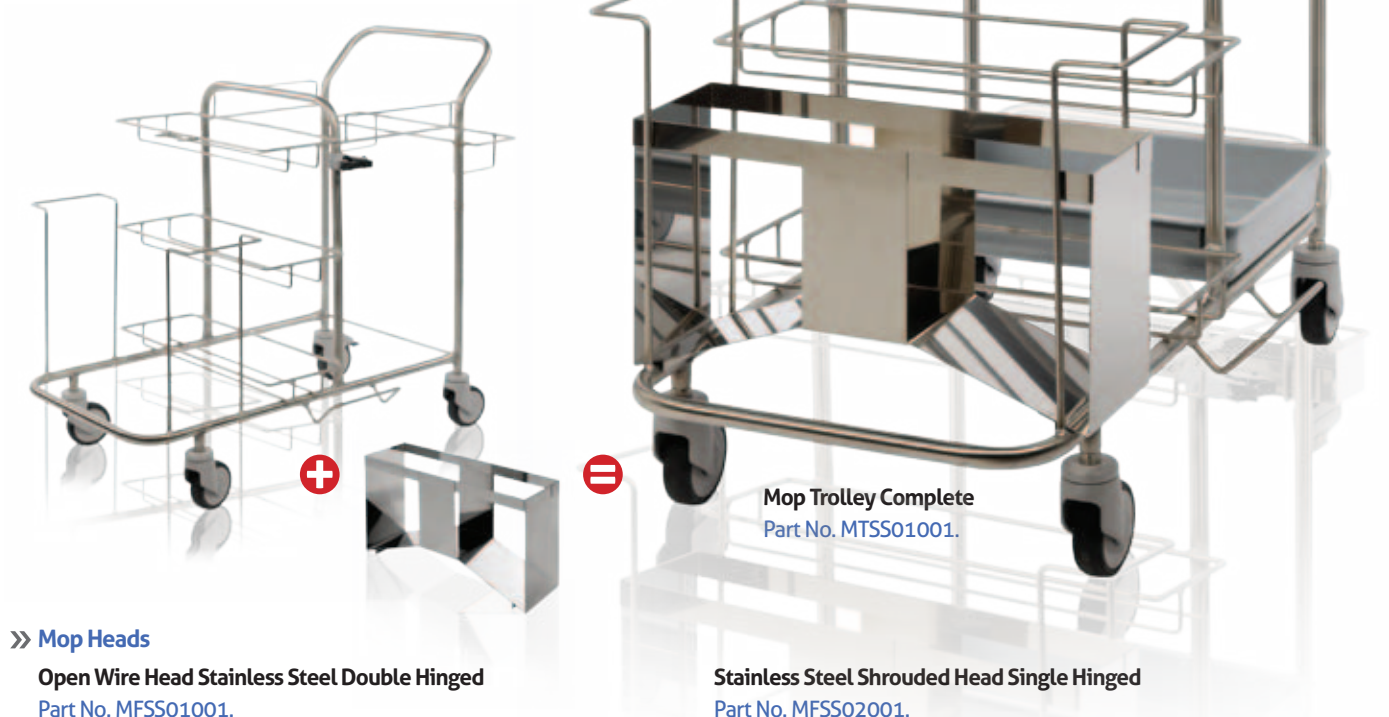


Cleaned mop undergoing inspection



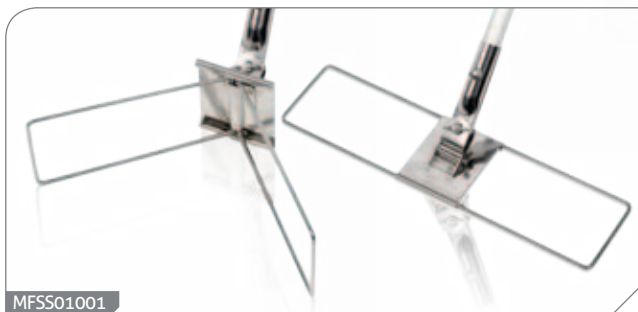
## » The Compliance 100® Large Scale Mopping System

### Types of hardware



#### » Mop Heads

**Open Wire Head Stainless Steel Double Hinged**  
Part No. MFSS01001.



**Stainless Steel Shrouded Head Single Hinged**  
Part No. MFSS02001.



#### » Handles & Bag Opener

**Stainless Handle Fixed Length 1.42 metre**  
Part No. MHSS01001.



**Aluminium Telescopic Handle**  
1.07 to 1.91 metres. Part No. MHSS02001.



**Safety Plastic Bag Opener & Carabineer**  
Part No. MHSS03001.





## » The Compliance 100® Large Scale Mopping System

# Types of mop available

### Short Pile Microfibre

#### Features and Benefits

Designed for cleanroom applications up to ISO Class 4, this very low shedding polyester microfibre mop has fully bound edges and due to the polyester reservoir holds enough disinfectant agent to provide cleaning and application coverage of 20M<sup>2</sup>. Gamma sterilisation compatible.



Short Pile Microfibre

### Polyester Open Loop

#### Features and Benefits

Designed for cleanroom applications up to ISO Class 4 this 100% polyester loop mop is also fully cleanroom constructed and holds enough disinfectant agent to provide cleaning and application coverage of 15M<sup>2</sup>. This is a suitable choice when soiling or fibre levels are high. Gamma sterilisation compatible.



Polyester Loop Mop

### Polyester / Viscose Twist Loop

#### Features and Benefits

Designed for high level food processing cleanroom 'grey areas' and janitorial duties, this tough polyester/viscose mop has fully bound edges and semi-rigid pockets. Due to the inherent hydrophilic properties of the media it is able to provide cleaner/disinfectant application coverage of 20M<sup>2</sup> per impregnated mop (subject to soil challenge levels).



Polyester / Viscose Twist Loop Mop

### Leasing Options

The system may be leased from Micronclean with any of the three mop types, in packs of 5, 10, 15 or 20 mops, impregnated or dry.

To facilitate deep cleans or residue removal programmes, a temporary hire of (additional) mops can be ordered or scheduled. This ensures lower running costs and adds flexibility.

Leasing Options	Microfibre Mop	Polyester Loop Mop	Polyviscose Mop
<b>Packs of 5</b> Rotational program of Alpha and Beta - mops on hire Dry mops on hire	MOPMW05SL MOPMD05SL	MOPLW05SL MOPLD05SL	MOPVW05NL MOPVD05NL
<b>Packs of 10</b> Rotational program of Alpha and Beta - mops on hire Dry mops on hire	MOPMW10SL MOPMD10SL	MOPLW10SL MOPLD10SL	MOPVW10NL MOPVD10NL
<b>Packs of 15</b> Rotational program of Alpha and Beta - mops on hire Dry mops on hire	MOPMW15SL MOPMD15SL	MOPLW15SL MOPLD15SL	MOPVW15NL MOPVD15NL
<b>Packs of 20</b> Rotational program of Alpha and Beta - mops on hire Dry mops on hire	MOPMW20SL MOPMD20SL	MOPLW20SL MOPLD20SL	MOPVW20NL MOPVD20NL
Temporary Hire Options			
<b>Packs of 15</b> Gamma mops are normally only used as temps mops Alpha mops on temporary hire Beta mops on temporary hire	MOPMG15ST MOPMB15ST MOPMD15ST	MOPLG15ST MOPLB15ST MOPLD15ST	MOPVG15NT MOPVB15NT MOPVD15NT

## » The Compliance 100® Large Scale Mopping System

# Large Scale Mopping System Chemistry

### Compliance 100® Alpha

A synergistic blend of quaternary ammonium compounds, Compliance 100® Alpha is a highly effective, colourless, odour-free, non-staining, non-tainting one-step disinfectant / detergent for the cleaning and disinfecting of all hard surfaces including: metal, glass, plastics, rubbers and polymers. The mode of action for Compliance 100® Alpha is via denaturing of micro-organism proteins and effects on the metabolic pathways. Compliance 100® Alpha is a broad-spectrum biocide and is effective against bacteria and fungi:

- Bacteria to EN 1276.
- Mycobacteria to EN 14348.
- Fungi to EN 1650.

### Compliance 100® Beta

Is the rotational cleanroom cleaner/ disinfectant agent to complement Compliance 100® Alpha. This product is a complex blend containing a unique amine based structure, blended with fully non-toxic, biodegradable detergent. The formulation does not contain any hazardous aldehydes or chlorine generating components.

The formulation is highly effective as a cleaner and disinfectant against bacteria, mycobacteria, fungi, viruses and spores. The mode of action exhibited by Compliance 100® Beta has been shown to be via disruption of the RNA of the micro-organisms and prevents resistance being built up. It is safe to use on any surface and is odourless and colourless.

Primary features attributable to Compliance 100® Beta are:

#### Suitable for cleanroom disinfection and cleaning - a one step process.

#### Highly effective over a wide range of flora:

- Bacteria to EN 1276 and EN 13697.
- Spores to EN 13704.
- Mycobacteria to EN 14348.
- Fungi to EN 1650.
- Viruses to EN 14476.

### Compliance 100® Gamma

A mildly alkaline detergent solution with no perfumes or dyes, designed specifically for residue removal in cleanrooms.

#### Large Scale Mopping System

Rotational Agents	Week				
	1	2	3	4	5
Compliance 100® Alpha					
Compliance 100® Beta					
Residual removal					
Compliance 100® Gamma	On request				

#### Rotational Information

Micronclean have developed an ideal rotational chemistry for the large scale system to ensure GMP compliance. Through careful study and selection the rotational chemistries of Compliance 100® Alpha and Compliance 100® Beta have properties which fit with industry best practices:

- Broad spectrum rapid biocides, capable of dealing with spores.
- Excellent cleaning ability.
- Wide chemical compatibility, including with each other.
- Very low non-volatile residues, odour, and colourless.
- Industry leading low toxicity profiles.

Being pre-impregnated into the system's mops also ensures :

- Correct dilution.
- Homogenous distribution.
- Traceable chemical identity.



Order Code	Description
ZSAP01500	500ml Compliance 100® Alpha Trigger Spray
ZSBT02500	500ml Compliance 100® Beta Trigger Spray



» Introduction to the Compact Mopping System

# Micronclean's Compliance 100<sup>®</sup> Compact Mopping System

Micronclean have been providing a sterile mopping system service to over 100 UK customers for the past 7 years.



Impregnation of mops is proving the most popular of the Compliance 100<sup>®</sup> products, bringing as it does controlled rotation of disinfectants, no wastage of expensive sterile disinfectants and the security of terminal sterilisation, plus no dirty buckets and equipment to clean and re-sterilise.

Following feedback from both industry and NHS users of Compliance 100<sup>®</sup> mopping systems, Micronclean have now provided additional services to address the requirements for 'Deep Cleaning' and 'Residue Removal'.

When looking at the cost per M<sup>2</sup>, recent evaluations of the system have shown that this is by far the most cost effective way to disinfect ISO Class 4 cleanrooms.



## » The Compliance 100® Mopping System - Process Rental

This unique compact Compliance 100® System removes the need for buckets, wringers or trolleys making it ideal for smaller cleanroom areas



Stage 1

Take and open a new bag of mop heads removing the return bag.



Stage 2

After removing the return bag, remove the pre-impregnated mop pack.



Stage 3

Ensuring the bag is self-standing, cut the top of the bag ready to remove a mop head.



Stage 4

Remove a mop head from the bag.



Stage 5

Place the mop head into the mop.



Stage 9

Micronclean pick up the soiled mops, clean, decontaminate, inspect and repackage them, then return them to you to be used again and again.



Stage 8

When all of the mop heads have been used, seal the bag and return to Micronclean ready for cleaning and return to you.



Stage 7

Once the 20M<sup>2</sup> area is mopped, remove the mop head and place into the return bag.



Stage 6

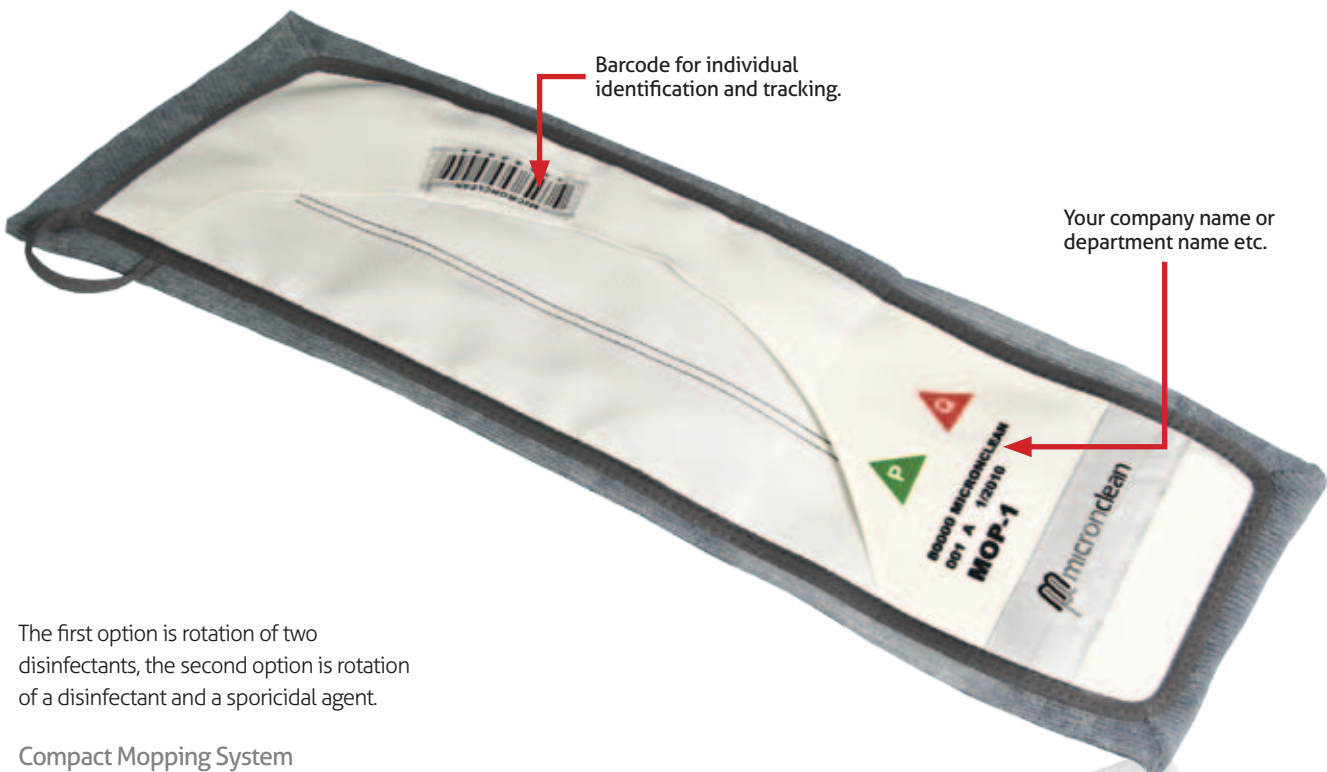
With the mop head firmly in place, begin mopping (max 20M<sup>2</sup> area per mop).

The only 'hardware' in the system is a folding mop head and handle. The system is designed for cleanroom use up to classification up to ISO Class 4. In this type of higher specification cleanroom, items entering should, where possible, be sterilised. Using the Compliance 100® System is simple and as illustrated above.



» How Our Rotational Biocide System Works

The Compact Micronclean impregnated mopping system consists of a rotation of two agents



The first option is rotation of two disinfectants, the second option is rotation of a disinfectant and a sporicidal agent.

Compact Mopping System

Rotational Agents	Week				
	1	2	3	4	5
Proceine					
Qceine					
Sporicide Reserve/Deep Clean					
Zyceine	On request				
Residual removal					
Viva Detergent	On request				

These cleanroom biocides are provided exclusively for this application by AGMA Ltd.

*Proceine® is a Polymeric Biguanide + Amphoteric Surfactant.*

*Qceine® is a Bis-biguanide + Quaternary Ammonium Compound.*

*Zyceine® is a Sporicidal Chlorine Releasing Agent.*



Construction - GMP Throughout

Mop handle and headframe construction - autoclavable and lightweight - this is the only 'hardware' required for this system.

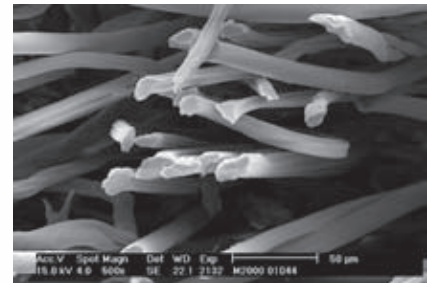
Aluminium telescopic handle

Polypropylene/polyamide headframe

### Security and Traceability - By Design

Micronclean's Compliance 100<sup>®</sup> Mopping System is designed just for GMP manufacturers. The set of mop heads issued to each customer is dedicated so you never receive other customers' mops. To ensure this, each mop is both barcoded (which is scanned in and out of Micronclean) and site-specifically labelled. The system meets the strict requirements of regulated industry by:

- Individual traceability.
- Simplifying Procedure Development (SOP).
- Validatability.



SEM POLYESTER FABRIC



SEM MICROFIBRE

Mops - 100% polyester and microfibre polyester construction.

- Autoclavable.
- Irradiatable.
- Extremely low linting 'endless fibre' technology.



Regular cleanroom disinfection, even with a mutually compatible rotational pair of biocides will eventually leave an amount of non-volatile residue, which periodically needs to be removed.



### Residue Removal

This task may be from monthly to six monthly, dependent upon the frequency of cleaning and the floor substrate type.

To ensure the same quality of equipment and process security as that provided by the Compliance 100® disinfection system, Micronclean are now providing a specialist cleanroom 'residue removal mop' impregnated with a mildly alkaline detergent.

*NB. These mops are hired on an 'as needed' basis and do not need to be contractualised. They are in effect a TEMPORARY HIRE to existing system customers.*

### The Dual-Sided Mop

This double-sided microfiber mop not only cleans a large surface area but also provides a light scrubbing action thanks to the dark blue strip's more rigid structure, whilst the grey microfibres remove and absorb residue to leave a surface ready for disinfection. This mop fits the existing handle and head.

### Proceine

#### Polymeric Biguanide + Amphoteric Surfactant

Providing a broad spectrum of activity, ideal for cleanrooms and pharmacies. 0.2 micron filtered and sterilised by Gamma irradiation, complete with supporting certification and visible detex marking.

### Qceine

#### Bis-biguanide + Quaternary Ammonium Compound

Qceine is specifically designed to be a complementary rotational alternative to Proceine and again provides a broad spectrum of activity, ideal for cleanrooms and pharmacies. 0.2 micron filtered and sterilised by Gamma irradiation, complete with supporting documentation and visible detex marking.



### Viva

The Cleaning Solution 'Viva' is a mildly alkaline detergent solution with no perfumes or dyes, designed specifically for residue removal in cleanrooms.

#### Order/Reference Codes

	Single Pouch	Multi-6 Pouch
	MRRV-1	MRRV-6

## » Contract Cleanroom Cleaning Service

To simplify the areas of cleaning that we offer our clients, we have broken down our areas of expertise into three distinct categories

- › Decontamination Cleans
- › Regular Cleans
- › Bespoke



### 1. Decontamination Cleans

This level of clean can apply to any new cleanroom construction, a major spill or any clean that falls outside of the normal parameters of a regular or bespoke clean. It may also apply to post-shutdown cleaning and any decontamination after planned and/or emergency maintenance. This level of cleaning is designed to remove heavy bioburdens and large amounts of particulates.

We provide all of our own fully certified equipment and consumables but can fall in line with your own procedures and materials where required.

We offer all stages of cleaning from vacuuming to cleaning of sensitive equipment in order to enable us to turn a new build into a fully functional, microbiologically in-specification facility.

Product quality is further enhanced via Micronclean's state-of-the-art storage facilities and own fleet of delivery vehicles enabling us to deliver right to the point of requirement.

### 2. Regular Cleans

As the name implies, this category of clean is carried out at a regular interval whether weekly, bi-weekly, monthly, bi-monthly etc., and can be carried out within your own time parameters or those established after consultation as being appropriate for your needs.

Regular cleans are designed to help maintain an already stable and fully functional facility. This type of clean is carried out in accordance with your own cleaning regime and methods and is designed to help maintain good practice within a cleanroom.

Cleaning can be carried out in accordance with your own gowning and transfer methodology and all our staff are highly trained to provide the best quality clean of your facility.





### 3. Bespoke

We appreciate that every cleanroom and area has its own unique set of cleaning needs and requirements. To this end we offer a totally bespoke and tailored cleaning regime to all of our clients if required.

Although we have recommended methods for each type of clean, we are completely flexible and are willing to work in conjunction with our clients in order to design and implement the best and most effective cleaning regimes.

We can perform a full cleaning audit and work with you to establish any weak areas within your cleaning activities and implement steps to improve your practices. From materials and solutions used, regularity of cleaning, training of internal staff or supply of external staff, we can tailor cleaning schedules to any requirement.

We work to our own Standard Operating Procedures (SOPs) and provide training records for all of our staff. We can work alongside our clients to design bespoke SOPs that are specific for each job and enable you to have complete control over any cleaning activities that are carried out within your own facility.

We are fully capable of carrying out any microbiological surface sampling that may be required before, during or after the cleaning. Contact plates can be carried out at our clients' request in order to illustrate the effectiveness of our cleaning.

» Training / SOP Validation

# Cleaning SOPs, Training, Documentation, Programme Design and Consultancy - we can tailor our services to your individual needs



## Quality Assurance Cleaning SOPs

For each clean carried out, whether one-off or routine, a Clean Plan will be drawn up for approval. This document will include site plans and define the cleaning procedures and materials to be used. Creating site-specific plans in this way provides flexibility, allowing consideration of individual customer requirements.

## Training

All cleaning staff are trained to key GMP requirements. Staff training includes good hygiene practice, cleanroom gowning technique and cleanroom cleaning methods. Specific staff training requirements for customer sites will be considered during the planning phase of a clean.

## Clean Documentation

On completion of a clean a Clean Record will be issued. The Clean Record contains a copy of the site Clean Plan, the results of pre- and post-clean environmental monitoring carried out, the batch information for all cleaning materials used and details of any deviations from the approved cleaning procedures, with a corrective action plan as appropriate.





### Cleaning Programme Design

Our experience in designing and implementing cleaning plans for all manner of cleanrooms and controlled environments allows us to advise on effective, practical approaches to cleaning.

We will work with you to build a cleaning plan that meets GMP and regulatory requirements whilst being designed to maximise procedural compliance by cleaning staff.



### Cleaning and Product Training

We can also offer training on how to make best use of Micronclean's Compliance 100® range. Training courses can be wholly tailored to individual customer requirements. Below are some examples of course content:

- GMP for cleanroom cleaners.
- Cleanroom cleaning product awareness training.
- How to design and implement a cleanroom cleaning plan.
- How to implement and use Micronclean's Compliance 100® Mopping System.

### Consultancy

As well as our complete cleanroom cleaning service we are also able to offer training and consultancy on the topic.

## » Cleanroom Equipment & Additional Services

# Production activities and research typically use extremely sensitive and important equipment to achieve the best results

### Cleanroom Equipment

We understand that equipment requires cleaning to a high level just as the cleanroom itself does, in some cases more so, and we can offer specialised cleaning of different types of equipment to the highest standard.

The most common piece of high grade equipment found in a cleanroom is an Isolator which will generally be kept to a significantly higher standard than that of the cleanroom. They are therefore considered critical pieces of equipment in many manufacturing processes and must be maintained to the appropriate standards. We can provide high level and bespoke cleaning to all different types of Isolators in conjunction with the customer's own instructions. Our operators have the knowledge and expertise to clean any grade of Isolator to a high standard in order to provide the client with the ideal conditions in which to operate.

Other common pieces of equipment we specialise in cleaning are centrifuges, balances, laminar air flow hoods and cleanroom furniture. We are capable of cleaning almost any item contained within a cleanroom and by matching the client's own needs and specific methods, we can achieve the highest levels of cleanliness.

### Additional Services

Support rooms and transfer hatches are critical areas that surround a cleanroom and if they are not properly maintained the risk of cross-contamination into the cleanroom increases.

In view of this we can also offer a reduced service that can help keep the areas adjacent to your cleanroom in a condition that is appropriate to your facility.

The standard of clean will be reduced from that of a typical cleanroom but should still be considered an essential piece of cleanroom maintenance nonetheless. We are happy to discuss each client's individual needs in regard to support areas and can incorporate this type of service into a cleanroom cleaning package.





» Testing & Validation

# Research, Development and Testing for validation, documentation and assurance



### Microbiological Testing Service (Pre/Post Clean).

We are able to offer microbiological testing pre- and post-clean in order to verify cleaning efficacy. Micronclean operate their own microbiological laboratory primarily servicing Micronclean production facilities. The laboratory is audited on a regular basis by customers from cleanroom industries including pharmaceutical and biotechnology, ensuring test systems remain in line with current best practice.

### Validation Disinfectant Testing (EN Norms)

Micronclean's range of cleanroom disinfectants have been tested using European standard test methods. This testing has proven the broad-spectrum bactericidal and fungicidal efficacy of the agents used. Please refer to the disinfectant section of this brochure. This testing has been supplemented by several years of experience successfully using these disinfectants in a wide variety of cleanroom environments.

### Alcohol Efficacy

Micronclean use 70% (v/v) aqueous solutions of isopropyl alcohol and denatured ethanol that meet the requirements of the European Pharmacopoeia. These solutions have been shown to give satisfactory disinfection test results using relevant European standard test methods - BS EN 1276:1997 (bactericidal suspension test), BS EN 1650:1998 (fungicidal suspension test) and BS EN 13697:2001 (bactericidal/fungicidal surface test).

### Sterility Assurance

All sterile cleaning and disinfection products in Micronclean's Compliance 100® range have a validated shelf-life; this ensures products are sterile and effective at the point of use. The Clean Documentation provided allows traceability back to batch records of all products used, including records of product sterilisation.





## Easy to Deal With

### Contact Micronclean

For any enquiries please contact Micronclean - we are happy to talk through any needs you may have.



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Web: [www.micronclean.eu](http://www.micronclean.eu)

Consumables website

