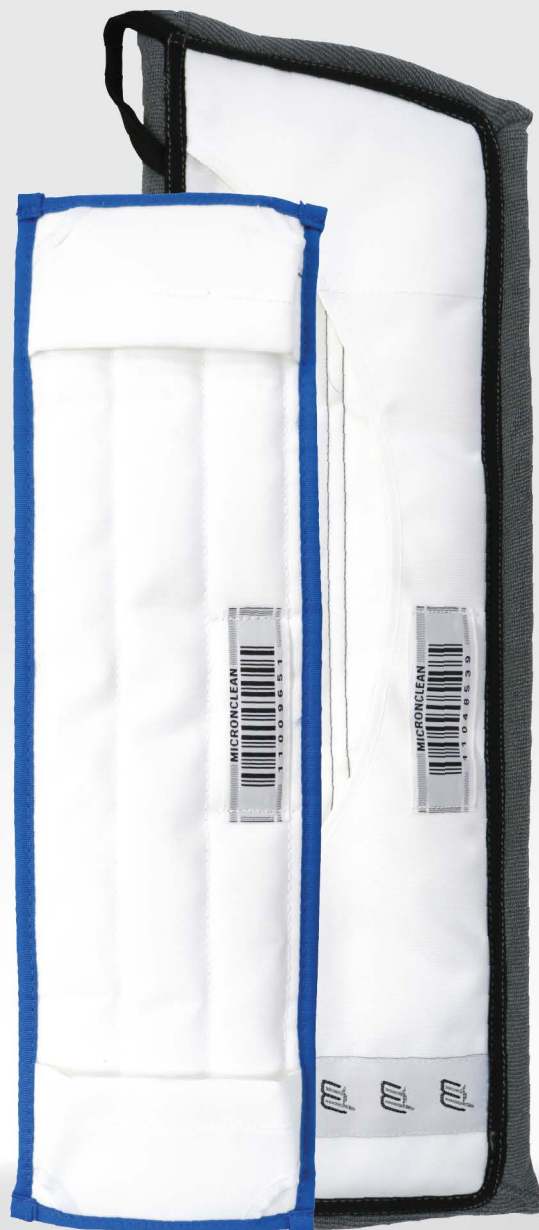


REUSABLE PRE-SATURATED CLEANROOM MOPPING SYSTEM



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INTRODUCTION

REUSABLE PRE-SATURATED LAUNDERED MOPPING SYSTEM

The Micronclean Large Scale and Compact Reusable Mopping Systems are designed for cleanroom use up to ISO 14644 Class 4, GMP Grade A or B. Both systems have been designed for ease of use and remove the need for mixing of chemicals within the cleanroom, disposal of waste fluids from within the cleanroom and the need to disinfect buckets and wringers, which are difficult to clean and sterilise.

Our patented mop system is available in two forms these being the Compact System which is ideally suited to cleanroom floors of less than 200m² and a Large Scale System which is targeted at cleanroom floors in excess of 200m². The Large Scale system is designed around a mop trolley which features a patented mop pouch dispenser and provides the carrying capacity for both clean and dirty mops to cover the larger floor area.

The heart of both of the Micronclean systems are the pre-saturated microfibre mops which are optimally dosed to give up to 20m² coverage before being processed through our ISO Class 4 Cleanroom laundry. The microfibre mops incorporate very low shedding 'endless fibre' technology which is suitable for repeated sterilisation by gamma irradiation. In addition, each mop is individually barcoded to give absolute traceability through our unique ProTrack System.

The Micronclean system of pre-saturated mops is fully GMP compliant in that it supports the routine cleaning of the floor using Delta neutral detergent before the application of a rotational disinfection schedule incorporating Alpha and Beta disinfectants.

The Micronclean system microfibre mops are also available in a laundered dry sterile condition.



INTRODUCTION

INTRODUCTION

The upcoming revision to EudraLex vol 4 covers Good Manufacturing Practice (GMP) guidelines and Annex 1 is specific to the manufacture of medicinal products. This update comes several years after its last revision and provides direction to the industry, reflecting best practice.

For cleanroom cleaning and disinfection regimes the key part to note is that the draft guidelines clearly separate the cleaning step from the subsequent disinfection.



Brussels, 22.8.2022
C(2022) 5938 final

GUIDELINES

The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use

4 Premises

Disinfection

4.33 The disinfection of cleanrooms is particularly important. They should be cleaned and disinfected thoroughly in accordance with a written programme. **For disinfection to be effective, prior cleaning to remove surface contamination should be performed.**

7 Personnel

7.11 The clothing and its quality should be appropriate for the process and the grade of the working area. It should be worn in such a way as to protect the product from contamination. Reusable garments should be replaced if damage is identified, or at a set frequency that is determined **during qualification studies. The qualification of garments should consider any necessary garment testing requirements, including damage to garments that may not be identified by visual inspection alone.**

7.14 Outdoor clothing (other than personal underwear) should not be brought into changing rooms leading directly to Grade B and C cleanrooms. **Facility suits, covering the full length of the arms and the legs, and socks covering the feet, should be worn before entry to change rooms for Grades B and C.**

7.15 Every operator entering Grade B or A areas **should gown into clean, sterilized protective garments (including eye coverings and masks)** of an appropriate size at each entry.

ROTATIONAL CLEANING AND DISINFECTION

DELTA NEUTRAL DETERGENT

Micronclean has recently brought to market a brand-new product Delta, which is a neutral detergent. Our Delta product has been developed to be fully compatible with our Alpha and Beta cleanroom disinfection regimes by having the following key features:



Low foaming formulation

this reduces the risk of streaks and staining when in use which could affect the subsequent disinfectant effectiveness.



Neutral (pH 6.5-7.5)

to ensure that it is non-corrosive and will not damage hard surfaces.



Supplied Pre-mixed and Dosed

to ensure a homogenous distribution of the active ingredient.



Manufactured with WFI

to ensure maximum cleanroom compatibility with cleanroom environment.



Gamma Irradiated

to give a sterile product with a shelf life of up to two-years depending on the application. For laundered pre-saturated mops the shelf life is one year from date of manufacture.

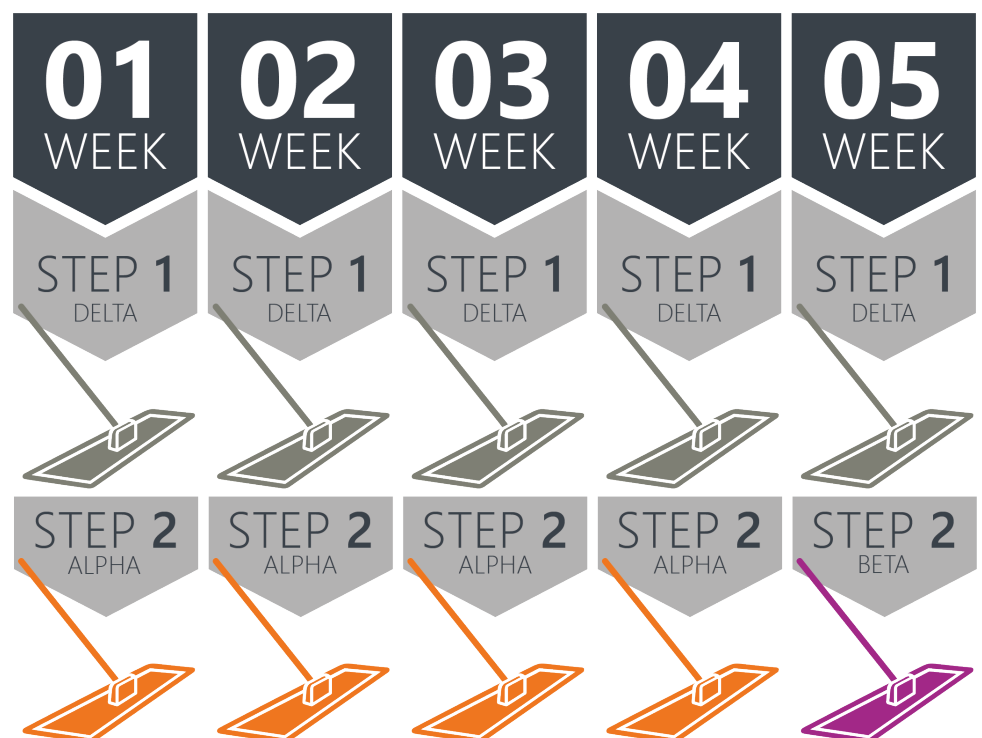
HOW TO USE

With both of our Laundered Mopping Systems, we would recommend the following regime to ensure the maximum benefit from our specially formulated detergent and disinfectants.

Week 1 Clean the floor by using Delta Mops followed by disinfection using Alpha Mops.

Weeks 2 to 4 As in Week 1 clean the floor by using Delta Mops followed by disinfection using Alpha Mops.

Week 5 As in the previous week clean the floor using Delta Mops but then use a Beta Mop as the rotational disinfection step to prevent the potential buildup of resistance within your environment.

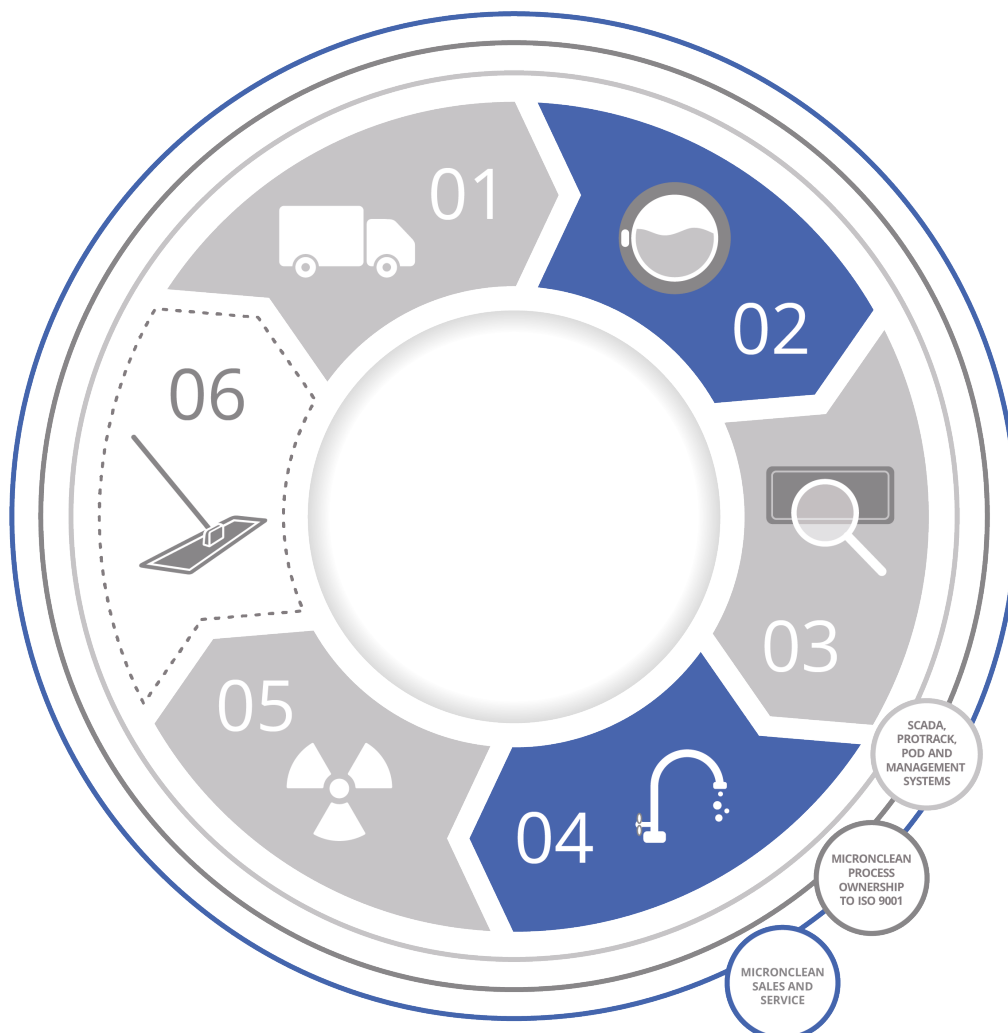


It is worth noting that as part of a Micronclean Laundered Mop contract the mops we supply to you will be in the correct order to match our proven regime without you having to worry.

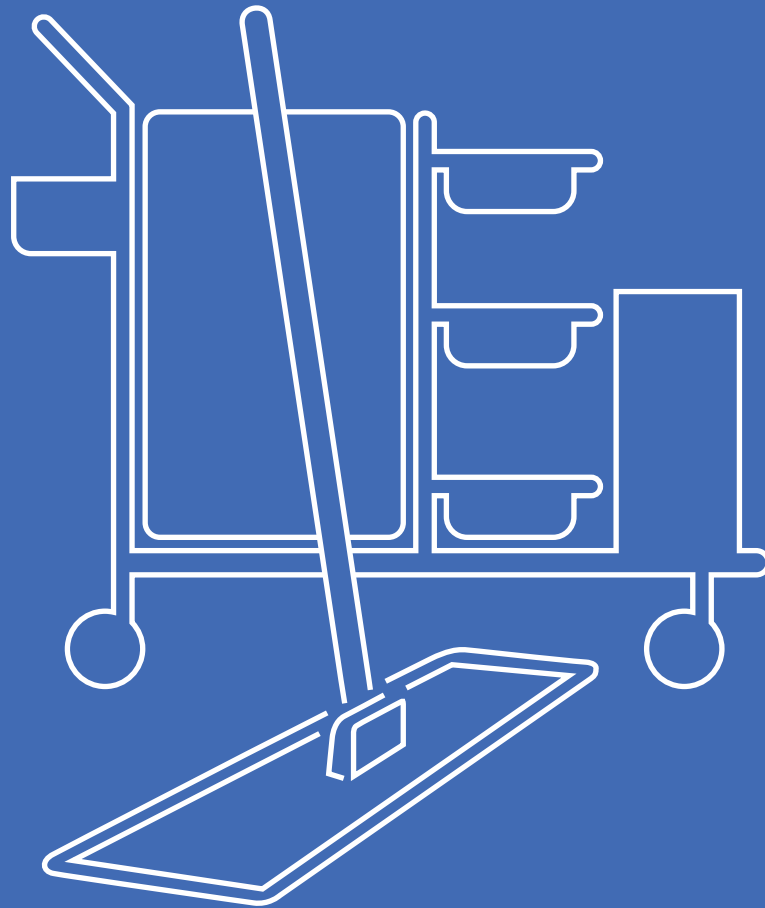
MOP DECONTAMINATION AND DOSING

Our state-of-the-art ISO Class 4 cleanroom laundry processes all the used microfibre mops using a dedicated specialised mop laundry cycle.

1. All used mops are returned using Micronclean's fleet of road vehicles.
2. The used mops scanned are scanned in using barcodes to ensure traceability before they are processed in barrier washing machines that are SCADA monitored and logged for critical parameters to ensure that they are clean before entering the cleanroom.
3. Inside the ISO Class 4 Cleanroom the clean mops are dried in SCADA monitored and logged tumble driers using HEPA filtered Air. The mops are then 100% visually inspected to ensure they are in the correct condition for putting in the pouches ahead of dosing. Any damaged mops are sent for repair by the sewing team ahead of being rewashed.
4. The dosing process is carried out in the ISO Class 4 cleanroom before the end of the pouch is heat sealed to prevent leakage and air ingress.
5. The pre-saturated mops are subjected to irradiation to ensure sterility before distribution.
6. The pre-saturated mops are returned using Micronclean's fleet of road vehicles in the correct sequence for you to use immediately.



LARGE SCALE MOP SYSTEM





LARGE SCALE MOP SYSTEM

MOPS

The Large Scale mopping system uses a specially developed short pile Microfibre mop head which has been optimised for repeated use in cleanroom applications up to ISO Class 4. The very low shedding 'endless fibre' polyester microfibre mop has fully bound edges and due to the inbuilt polyester reservoir holds enough liquid to give up to 20m² coverage. The mop is Gamma sterilisation compatible.

RENTAL OPTIONS/PACK SIZES AND CODES

Sterile Code	Description	Material	Mop Colour	Size	Pack Size
1Q1	Large Scale Pre-saturated mop for Alpha and Beta Sterile	Microfibre	Blue	One Size	5 or 10
1Q3	Large Scale Pre-saturated mop for Delta Sterile	Microfibre	Blue	One Size	5 or 10
1Q2	Large Scale Dry mop Sterile	Microfibre	Blue	One Size	5 or 10

On a Micronclean Laundered Mop contract the mops we supply to you will be in the correct order to match our proven rotation of Alpha and Beta.



LARGE SCALE MOP SYSTEM HARDWARE

Designed to work alongside the Large Scale Laundered Mopping System.
Fully autoclavable.

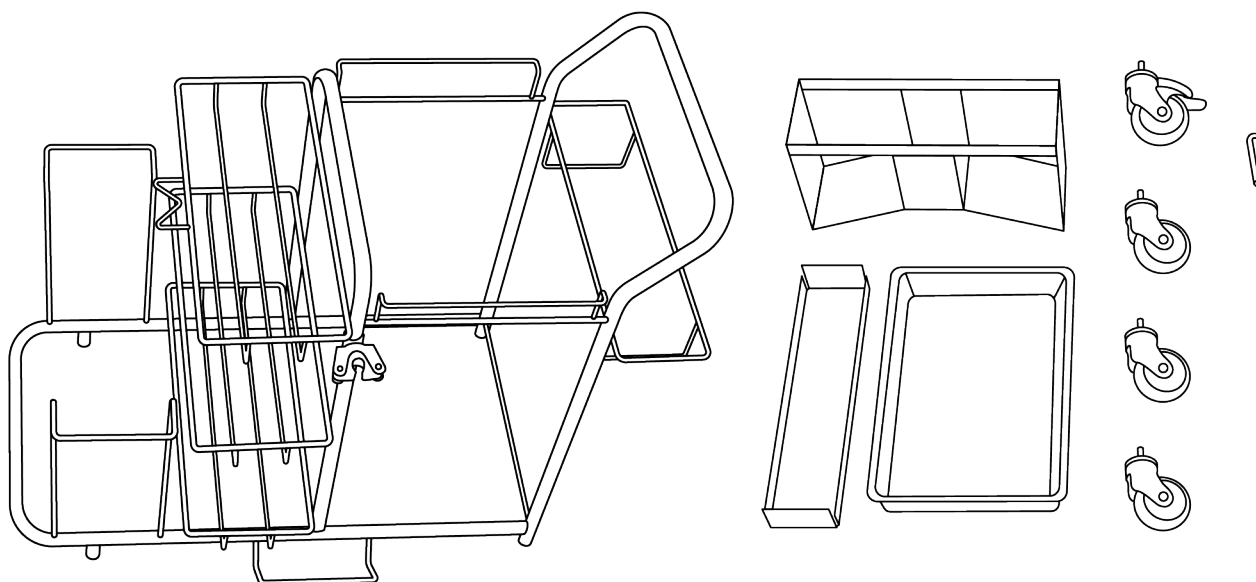
MOP TROLLEY, HANDLES AND FRAMES

Product Code	Description	Size	Pack Qty	Case Qty
MTSS01001	Mop Trolley	One Size	EA	EA
MFSS01001	Lightweight Locking Mop Frame	One Size	EA	EA
MFSS79226	Stainless Steel Shrouded Mop Frame (with wing nut)	One Size	EA	EA
MHSS02001	PureGuard Stainless Steel Fixed Length Mop Handle (142cm)	One Size	EA	EA
MHSS02002	PureGuard Aluminium Adjustable Mop Handle Graphite Grey	One Size	EA	EA

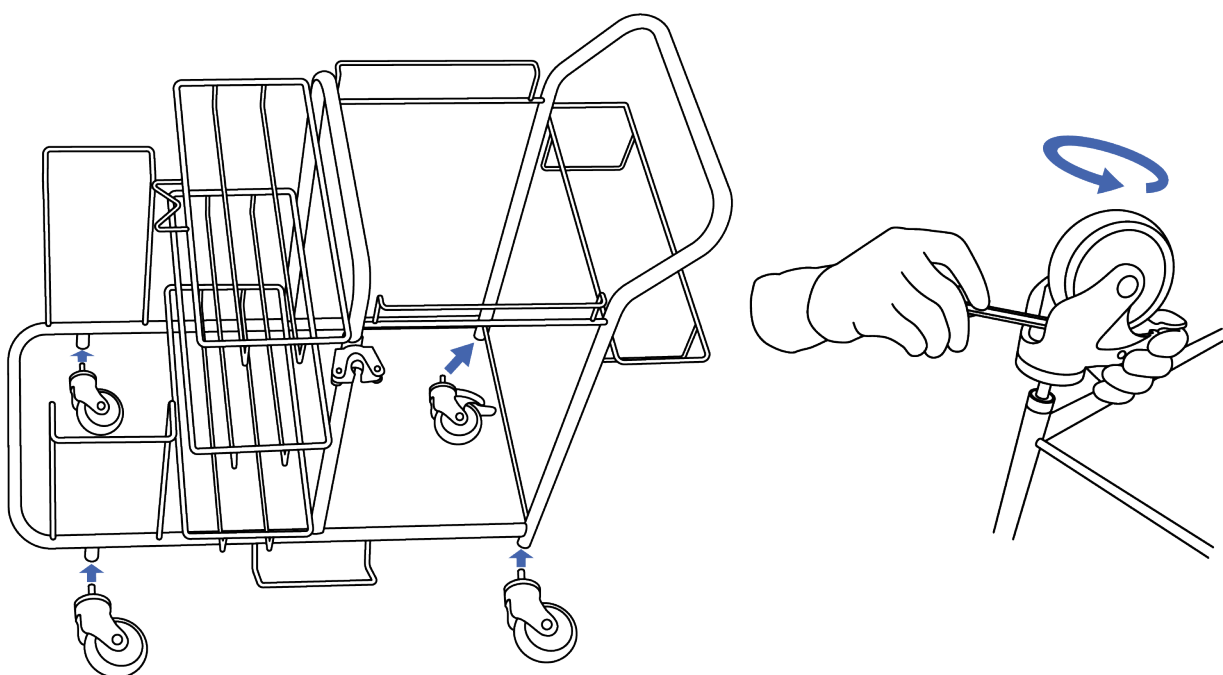
LARGE SCALE MOP SYSTEM

HOW TO ASSEMBLE A CLEANROOM MOP TROLLEY

1 Contents



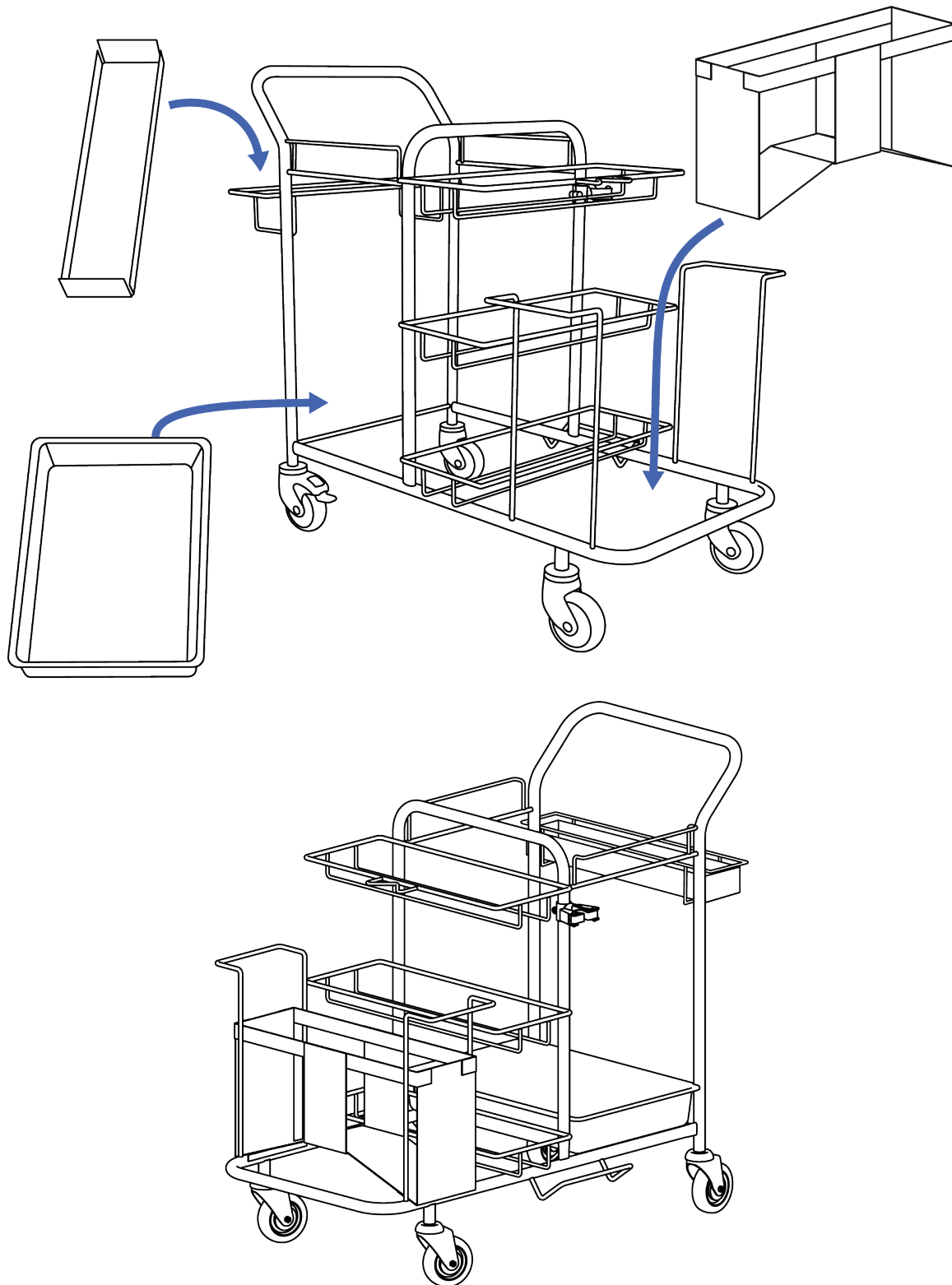
2 Attaching the wheels



LARGE SCALE MOP SYSTEM

HOW TO ASSEMBLE A CLEANROOM MOP TROLLEY

3 Positioning the pieces



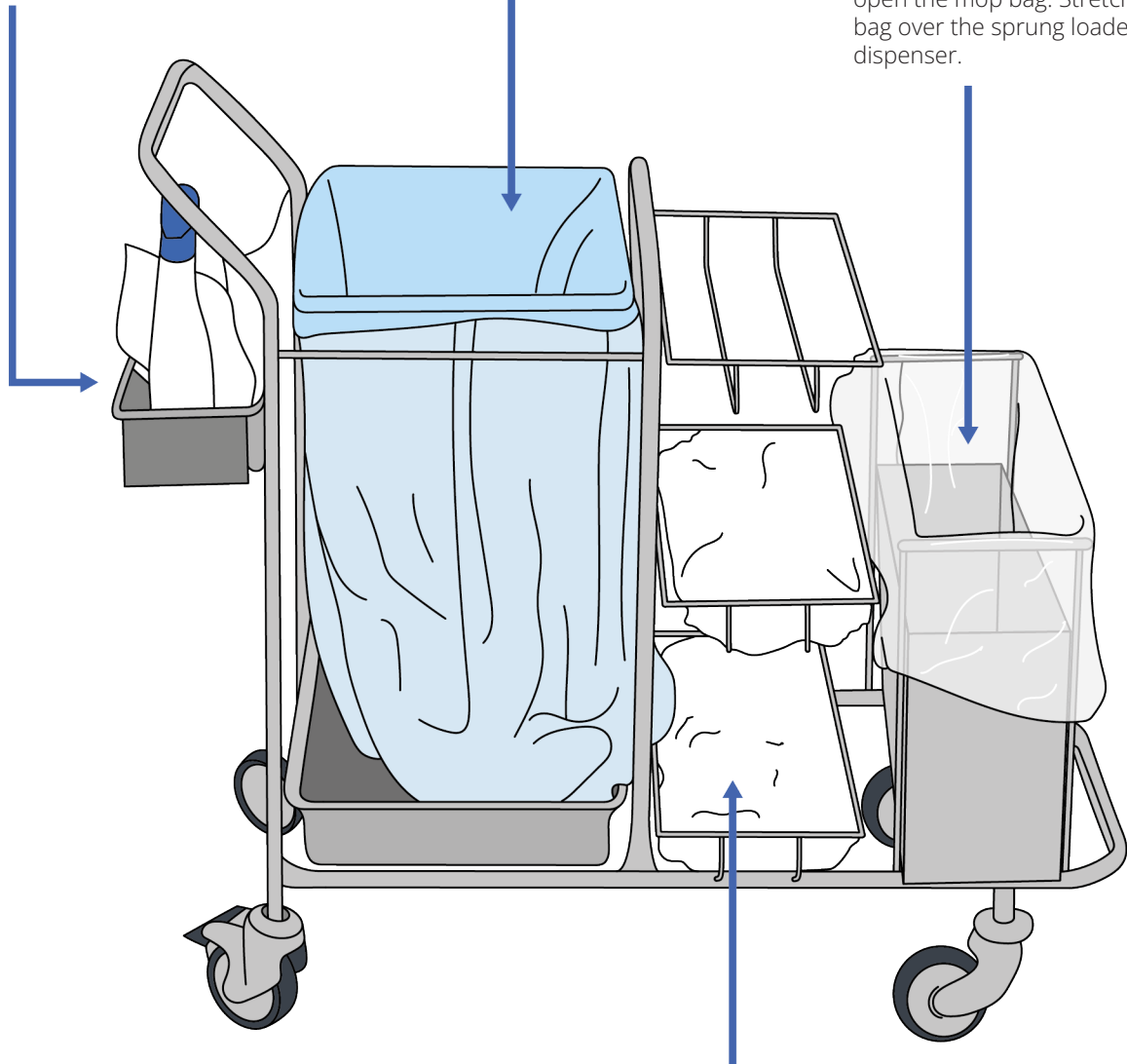
LARGE SCALE MOP SYSTEM

HOW TO SET UP A CLEANROOM MOP TROLLEY

Tray stores trigger sprays and wipes which are also available from Micronclean.

Ensure the draw string net bag sits inside the waste plastic bag and that both are pulled over the metal frame. You can tighten the bag over the frame by adjusting the draw string.

Remove the outer bag of a sealed mop pack and insert into the dispenser attached to the trolley. Using a cleanroom compatible cutter, open the mop bag. Stretch the bag over the sprung loaded dispenser.

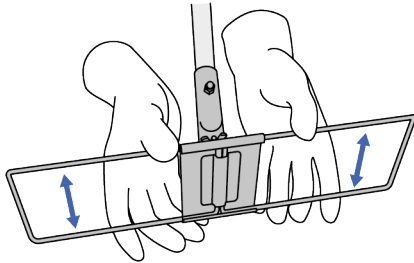


Sealed mop pack storage.
3 open wire shelves with a
capacity of 60 mops.

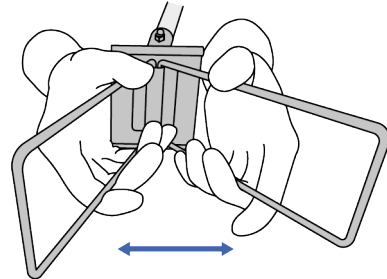
LARGE SCALE MOP SYSTEM

HOW TO USE THE LARGE SCALE MOPPING SYSTEM

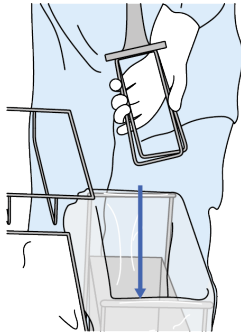
- 1** Squeeze the metal frame together.



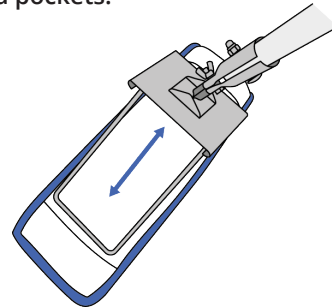
- 2** Push the two sides together.



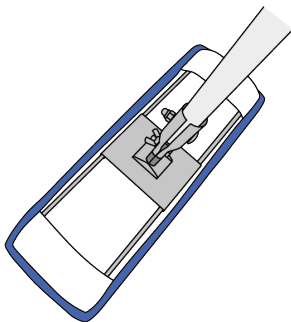
- 3** Put the mop frame into the mop dispenser on the front of the trolley.



- 4** Push down onto the mop head so that the two sides of the frame separate towards the end pockets.



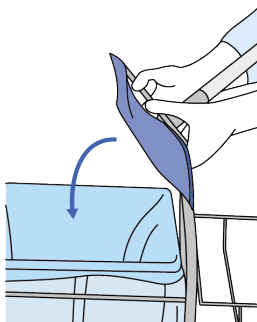
- 5** Push the frame into the pockets. Ensure that the mop frame clicks into place.



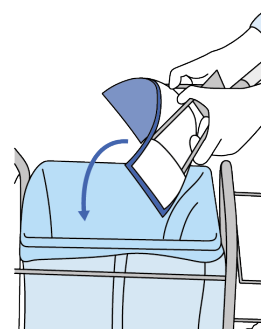
- 6** Mop the floor/walls in accordance with aseptic techniques. A single mop cleans up to 20m².



- 7** Once the mop is used, squeeze the frame as before over the net bag. Avoid touching the mop head.



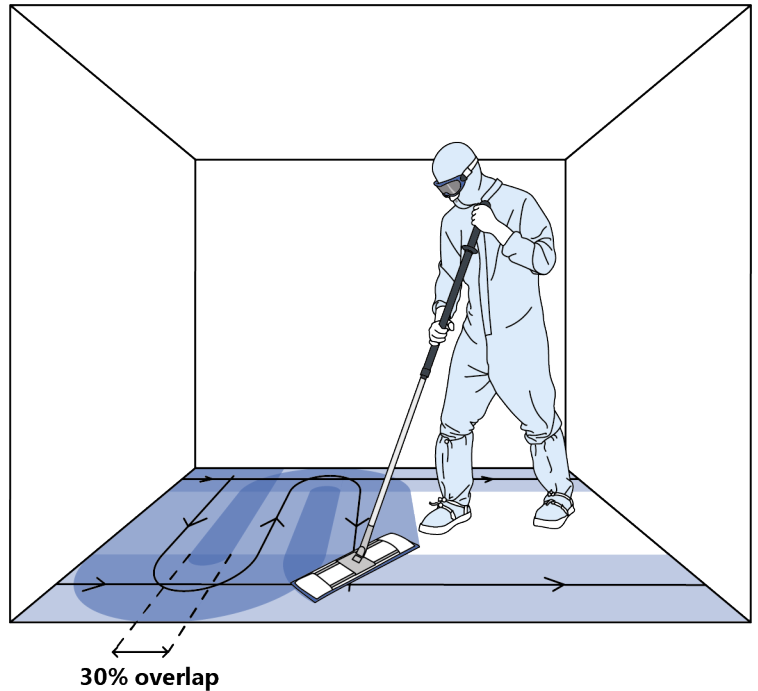
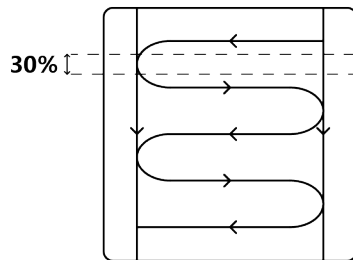
- 8** Let the mop fall into net bag. Repeat the process with your next mop.



LARGE SCALE MOP SYSTEM HOW TO MOP A CLEANROOM

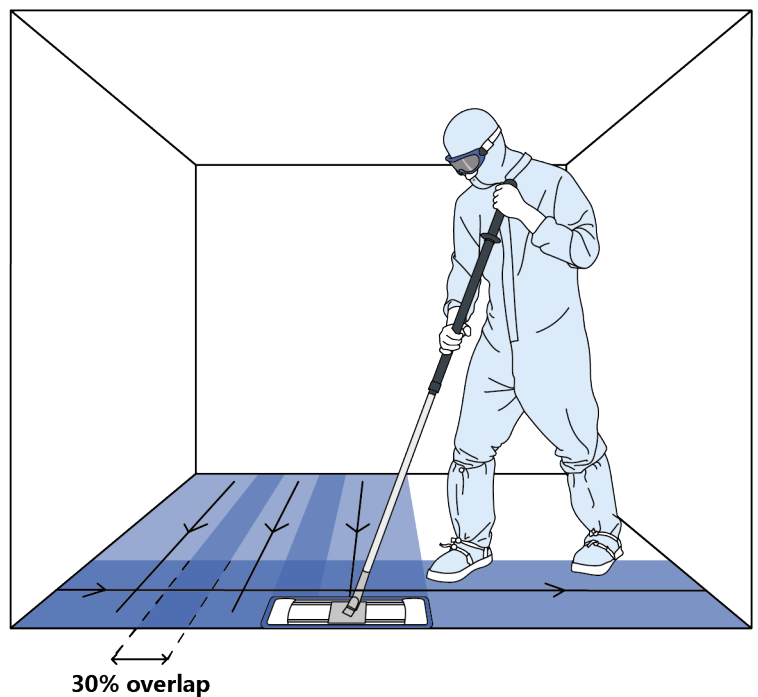
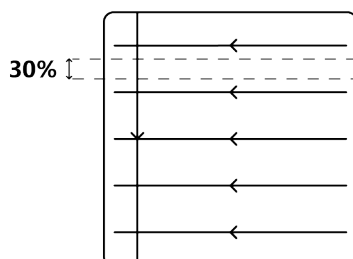
The s-curve method

- Mop the two edges either side of your cleanroom area.
- To reduce contamination, avoid stepping on any cleaned areas.
- Mop across your cleanroom area using an s-shape. Keep lines as neat as possible.
- Overlap paths by 30%.

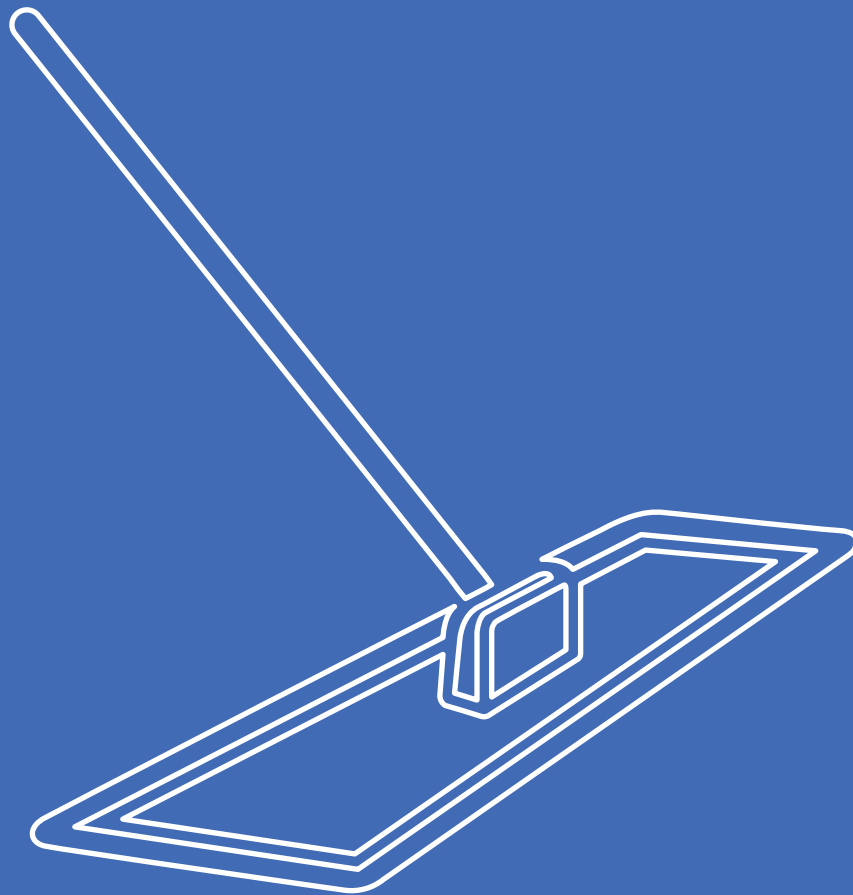


The place and pull method

- Place your mop at the edge of your cleanroom area and mop across a straight line.
- Repeat the straight lines, ensuring paths overlap by 30%.
- To reduce contamination, avoid stepping on any cleaned areas.
- Finally mop along the edge of the room.



COMPACT MOP SYSTEM





COMPACT MOP SYSTEM

MOPS AND HARDWARE

The compact mopping system a specially developed short pile Microfibre mop head which has been optimised for repeated use in cleanroom applications up to ISO Class 4. The very low shedding 'endless fibre' polyester microfibre mop has fully bound edges and due to the inbuilt polyester reservoir holds enough liquid to given proven coverage of up to 20m². The mop is Gamma sterilisation compatible.

RENTAL OPTIONS/PACK SIZES AND CODES

Sterile Code	Description	Material	Mop Colour	Size	Pack Size
1W1	Compact Pre-saturated mop for Alpha and Beta Sterile	Microfibre	Grey	One Size	1
1VA	Compact Pre-saturated mop for Delta Sterile	Microfibre	Grey	One Size	1
1DA	Compact Dry Mop Sterile	Microfibre	Grey	One Size	1
MOPH001	Telescopic Handle	Aluminium/Plastic	N/A	One Size	1
MOPF002	Mop Head	Plastic/Stainless Steel	N/A	One Size	1

On a Micronclean Laundered Mop contract the mops we supply to you will be in the correct order to match our proven rotation of Alpha and Beta.

COMPACT MOP SYSTEM

HOW TO USE THE COMPACT MOPPING SYSTEM

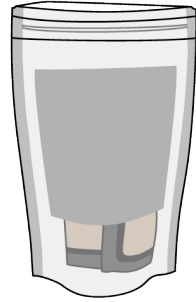
1 Open the secondary bag.



2 Open the new pouch.



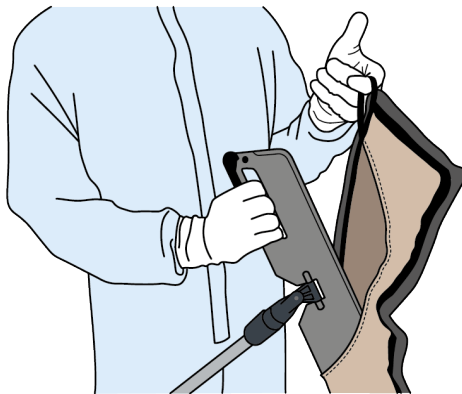
3 Place the pouch in a standing position.



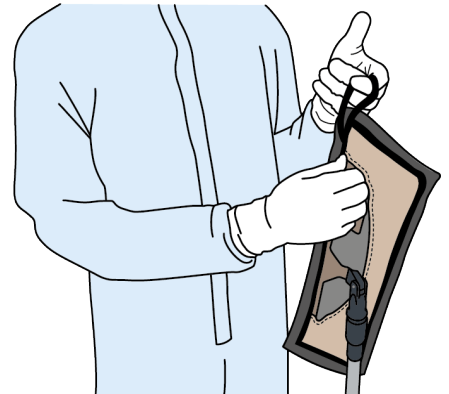
4 Remove a single mop head from the pouch using the loop provided.



5 Fix the single mop head into the mop frame.



6 Tighten up the single mop head.



7 Clean a maximum of 20m².



8 Discard the used mop head into the empty pouch.



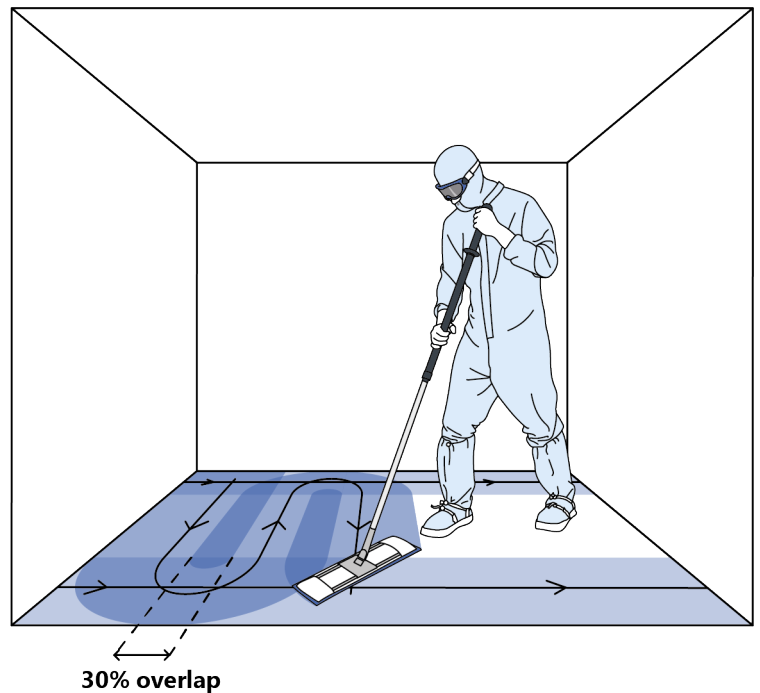
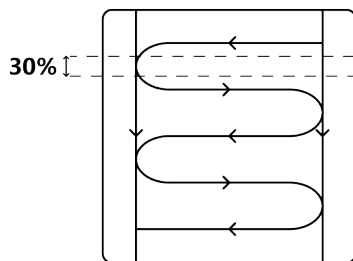
9 Ensure used mops are returned to Micronclean.



COMPACT MOP SYSTEM HOW TO MOP A CLEANROOM

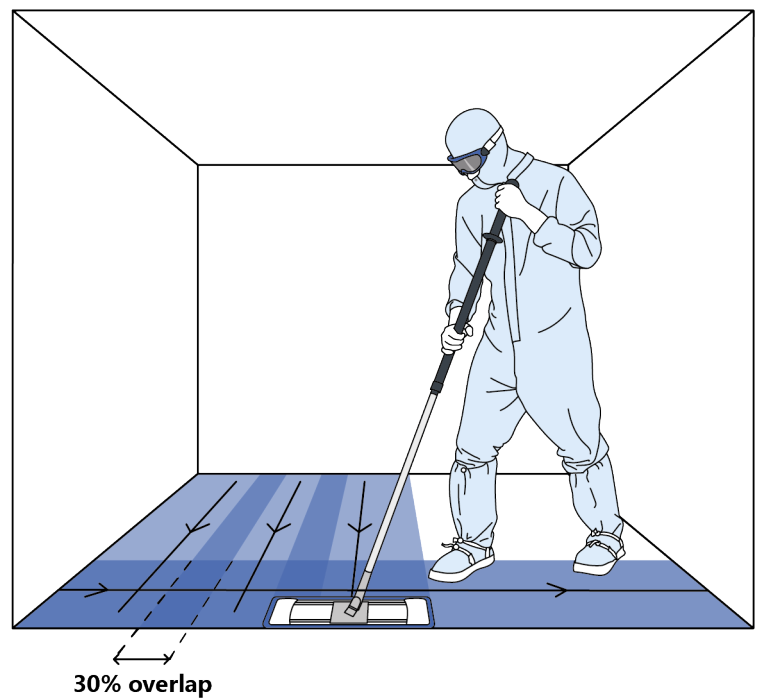
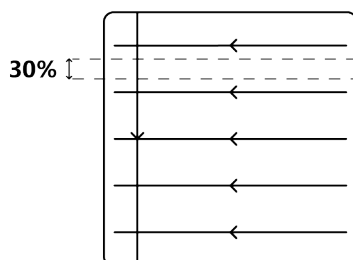
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The place and pull method

- Place your mop at the edge of your cleanroom area and mop across a straight line.
- Repeat the straight lines, ensuring paths overlap by 30%.
- To reduce contamination, avoid stepping on any cleaned areas.
- Finally mop along the edge of the room.



MICRONCLEAN SERVICE

KEGNESS SITE

Micronclean's ISO Class 4 (EU GMP grade B) facility has been purpose-built to exceed the needs of today's modern cleanroom requirements.

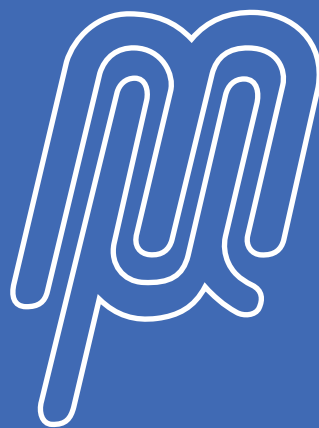
Using Micronclean's dedicated validated cleanroom wash programs, garments, mops and goggles are processed using barrier washing machines into our ISO Class 4 cleanroom (EU GMP grade B). The washed cleanroom items are then placed into positive pressure, HEPA filtered tumble dryers to complete processing and aid final particulate removal. The Cleanroom items are then folded (if required) and packaged before the addition of batch information for full traceability.

UK WIDE DISTRIBUTION

From our Lincolnshire laundries, our own fleet of vehicles run overnight trunking routes to service our regional transport centres in the South East, South West, North East, North West and Scotland. From these regional hubs our fleet then undertake local tailored deliveries to ensure that you get all your cleanroom items including consumables when you want them.

As a result, our transport network covers the whole of the UK ensuring that all our customers get an efficient, cost effective and reliable flow of cleanroom items.





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MMSUK 09/2023