

INDIAN CLEANROOM LAUNDRY

MICRONCLEAN INDIA



CONTENTS

INTRODUCTION	01
KEY FOCUS AREAS	02
GARMENT RENTAL MODEL	03
BENEFITS	04
PROTRACK	05
GARMENT RENTAL AND SERVICE MODEL	06
LAUNDRY FLOWCHART	07
SOILED SIDE	08
LAUNDRY	09
AUTOCLAVE / PACKING	10
DISTRIBUTION	11
UTILITIES BLOCK	12
CLEANROOM GARMENTS	13
STANDARD CLEANROOM COVERALL	14
STANDARD CLEANROOM BOOT	15
STANDARD CLEANROOM HOOD	16
REUSABLE CLEANROOM SOCK	17
EXTRA LONG COAT WITH ELASTICATED CUFF	18
EXTRA LONG COAT WITH STUD	18
LAB COAT	19
UNDERGARMENT TUNIC	20
UNDERGARMENT TROUSER	21
TOP WITH STUD FASTENING AT WRIST	22
TROUSERS WITH ELASTICATED WAIST	23
HAT	24
VALIDATION	25



INTRODUCTION

Micronclean is the UK's leading cleanroom laundry supplier providing specialist workwear and cleanroom laundry services to companies in the pharma, healthcare, microelectronics, aerospace and semiconductor industries. With a 65% market share our ISO Class 4 and 6 laundries provide cleanroom clothing to all the large UK based pharmaceutical companies including Baxter Healthcare, Astra Zeneca, GSK, Mylan, Wockhardt, Ipsen, Novartis, Fresenius Kabi and Dr Reddy's.

As a UK based company Micronclean currently has a £35m turnover but our aspiration is to reach £100m by 2027, with growth from all sectors we operate in but the largest forecast growth will be in the Indian Cleanroom Laundry business alongside International Consumables sales.

From initial research we found that despite India's large and rapidly growing pharmaceutical industry, there were no commercial cleanroom laundries; it was all served by in-house, on-premise laundries that were not maintaining compliance with regulatory requirements. As a result we felt that Micronclean could export our existing technology in a turn key format so that from day one of operation our cleanroom laundry customers could benefit from our 40 plus years of building and running GMP compliant laundries.

As a result, Micronclean acquired a three-acre site at Vemagal to the North East of Bangalore. The build became operational in September 2021. Phase one delivered two cleanrooms with a total processing capacity of 80,000 garments per week. Phase two will double this capacity. From this base we are able to offer a daily delivery service to the pharmaceutical hubs of Bangalore, Chennai, Goa, Hyderabad, Pune and Vishakhapatnam.

This brochure introduces the key features of a cleanroom laundry covering the layout and capability of the cleanroom laundry itself, the key features of the laundry rental service and illustrates the standard cleanroom garment offering.

Simon Fry
Chairman
Micronclean



KEY FOCUS AREAS

TARGET SECTORS

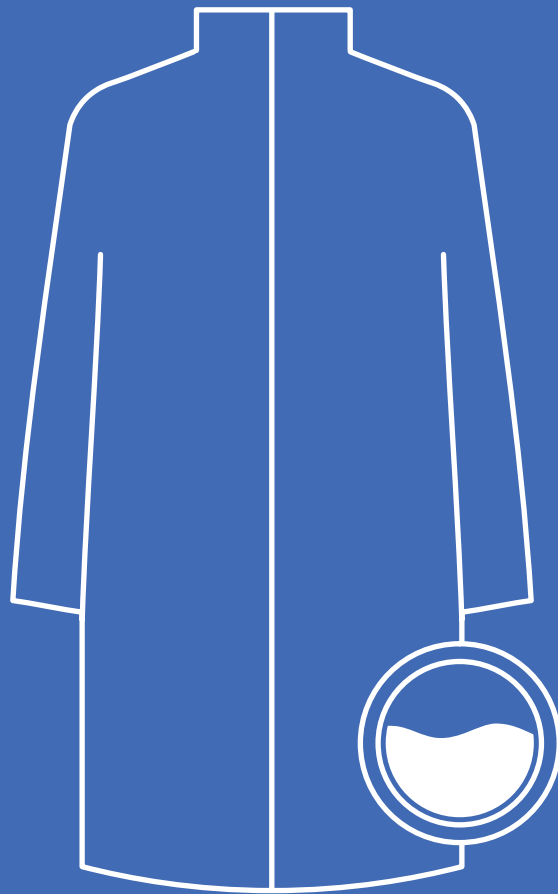
The Micronclean Cleanroom Laundry in Bangalore operates to cGMP Grade B / ISO 14644 class 5 standards and produces cleanroom garments suitable for use in sectors where biocontamination control is critical. Typical target sectors include the aseptic production of injectable pharmaceuticals, pharmaceutical tableting plants, other biotechnology products as well as semi-conductor production.

Typically, the standards required for these sectors can be summarised as the provision of cleanroom garments which are:

- Visually clean;
- Free from physical contamination;
- Processed to have a very low level of residual particulate contamination (compliant with Class A of ASTM F51-00 / Category I of IEST RP CC 003);
- If damaged, repaired to a standard compatible for cleanroom end-use and in line with customer requirements (where specified);
- Processed to have a very low bioburden;
- Produced in an environment designed to minimise physical, chemical and biological contamination and monitored for particulate and microbiological contamination to Grade B of the cGMP guidelines;
- Sterilised using autoclaves if required.
- Compliant to revised EU GMP Annex 1 guidelines "Manufacture of Sterile Medicinal Products".



GARMENT RENTAL MODEL



GARMENT RENTAL MODEL BENEFITS

CLEAN WORKWEAR ALWAYS AVAILABLE

With our cleanroom laundry service, you can ensure that all your employees always have clean compliant garments available as we will deliver the garments on our fleet of Micronclean vehicles straight to their lockers on your site. In addition, we will take away used garments ready for processing in our custom built cGMP Grade B / ISO 14644 Class 5 cleanroom laundry facility.

GMP COMPLIANT PRACTICES

Our cleanroom laundry in Bangalore has been designed from the ground up to be a dedicated cGMP Grade B / ISO 14644 Class 5 facility. The processes within the laundry are based on existing UK best practice and will deliver:

- 100% visual inspection of all garment prior to processing;
- Validated double sided repairs to damaged garments;
- Validated thermal disinfection cycles giving 5 log reductions in bioburden;
- Validated thermal drying cycles to ensure that your garments comply Class A of ASTM F51-00 in terms of particulate cleanliness;
- Validated terminal sterilisation by Autoclave to ISO17665.

Within the laundry all the garments will be tracked using RFID tags in conjunction with our bespoke Protrack software. The RFID tag in each garment will ensure traceability back to batch validation data captured on our SCADA system and will maintain a complete garment history as well as delivering both routine and customised usage reports directly to you.

We also have a system that tracks the garment from our laundry, through our dedicated delivery fleet to your premises minimising the possibility of lost garments or missed deliveries. In this way working in partnership with you we can remove your garment worries in connection with regulatory body inspections (FDA, MHRA, EMA).



1. Collection of Used Cleanroom Garments
2. Full Inspection
3. Validated repairs if required
4. Cleanroom Garments are decontaminated in an ISO GMP 5/Grade B facility
5. Terminal Sterilisation by autoclave
6. Scanned out and transport to your site
7. Ready for you to use

SAVING TIME AND MONEY

Our dedicated cleanroom laundry service includes everything from measuring your staff, buying the garments, providing the lockers, cGMP cleanroom laundry practices, garment repair, delivery, routine replacement (if required) and environmentally friendly garment disposal at the end of life. This means you can focus on your core business while we focus on ours.

In addition, our inclusive garment rental model means that you don't need any capital investments to get started and with no hidden charges during the contracts lifetime you only have to pay a regular monthly charge.

THE SUSTAINABLE CHOICE

We expect your laundered garments to have an average service life of 100 cycles in normal use which equates to a massive reduction in the amount of waste you have to deal with.

Our cleanroom laundry has been designed from the outset to be a Zero Liquid Discharge (ZLD) facility to minimise our use of water and will utilise 150 KW of solar panels to reduce our use of electricity.

Additionally, the provision within the facility of back-up boilers and diesel generators means that we are delivering not only a sustainable solution but also an inherently robust process which ensures that you will always have your clean garments when you need them.

GARMENT RENTAL MODEL PROTRACK

PROTRACK

Micronclean use RFID transponders to track all of your cleanroom garments through our entire process. The advantage of an RFID tag over a barcode is that removes the need for direct line of sight to scan and opens the possibility of bulk scanning if this generates process benefits.

Our unique in-house developed Protrack software makes full use of the advantages of RFID scanning. The fundamental difference between Protrack and most other laundry systems is that Protrack manages the individual garment and allows a high level of traceability whereas most other systems treat individual items as part of a pool. In this way we can monitor your contract and garment usage at every level from "customer" (all your garments) down to an individual garment (locker number, size, age, repairs and usage etc.).

As the Cleanroom Laundry processing is highly automated, each garment's status and location is known throughout the facility e.g. checking in, inspection, repair, wash process, drying, folding, primary packing, autoclave sterilisation, secondary bagging, dispatch and delivery.

Garments are assembled into a batch with the whole batch being parametrically released from the wash, dry and autoclave cycles. All batch validation data is monitored on a SCADA system along with the cleanroom environmental parameters. The RFID tag allows the specific batch validation data to be retrieved for any garment and for Micronclean to perform a batch recall if this were ever required. This data is essential for customers to demonstrate full GMP compliance.

In this way the Protrack software allows us to handle all the requirement of Annex 1 alongside individual customer contract requirements such as:



Inspection criteria can be set to meet the customers' needs so that the individual garment details are presented at inspection.

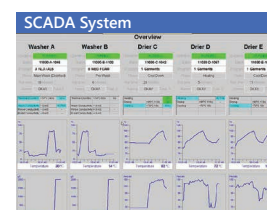


Repair criteria can be set which cover validated repair techniques and control the number and size of repairs and could invoke routine replacement of the garment.



Customised wash, dry and autoclave programmes that could include pre-set garment life criteria, wash cycles and detergent control, drying times and temperatures and autoclave process information.

Micronclean's SCADA system confirms parametric batch release for wash, dry and autoclave processes which is automatically available through Protrack. This is a powerful added value feature which demonstrate to auditors and regulators that the required garment management system controls are in place.



Alongside the garment web portal which allows instant access to garment tracking information the system allows us automatically generate reports that cover;

- Contract overview including number of garments, usage and charges.
- Garment information including issue date, last scan and number of scans.
- Repair information, by wearer, department, time period, cost centre.
- KPI dashboards that provide a KPI based overview as to the status of your contract.

GARMENT RENTAL AND SERVICE MODEL

MICRONCLEAN GARMENT RENTAL AND SERVICE MODEL

A cleanroom garment rental service is split into two parts covering initial supply followed by a seamless transition into routine servicing which includes collection, decontamination, sterilisation and delivery. The initial supply phase covers the specification, sourcing, purchase and supply of fully prepared ready to wear cleanroom garments.



Initial Meeting

Understanding of size and scale of contract and timescales required.



Detailed Site Survey

Discuss and understand local site issues including specific site requirements including delivery restrictions, number of changes and special processing requirements.
(Scope of Services)



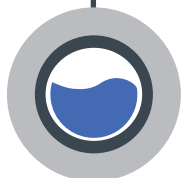
On-Site Measurement

At an agreed time, we will come to your site and measure all your staff.
This process has to be fully completed before we can order the garments.



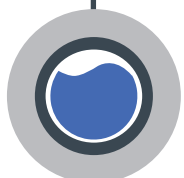
Order Garments

After measurement we will order all your required garments.
Non-standard garments will have a much longer lead time than standard garments.



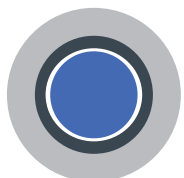
Tag, Label and Process

Before a garment is issued we will apply any required badges and install the RFID tag.
We will then register the garment in our 'Protrack' system so that we can monitor its entire life.
The garment is then given its first decontamination to make it ready for installation.



Initial Installation

At a time to suit you we will dispatch the finished garments to your site and our personnel will install them to ensure a seamless transition.

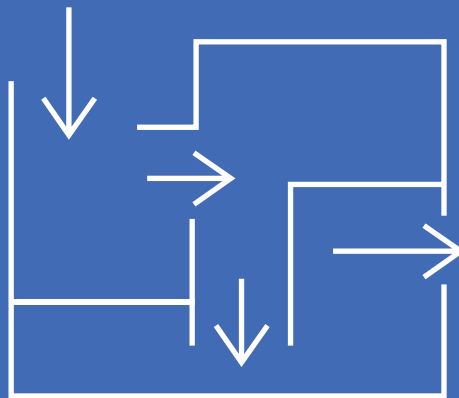


Routine Servicing

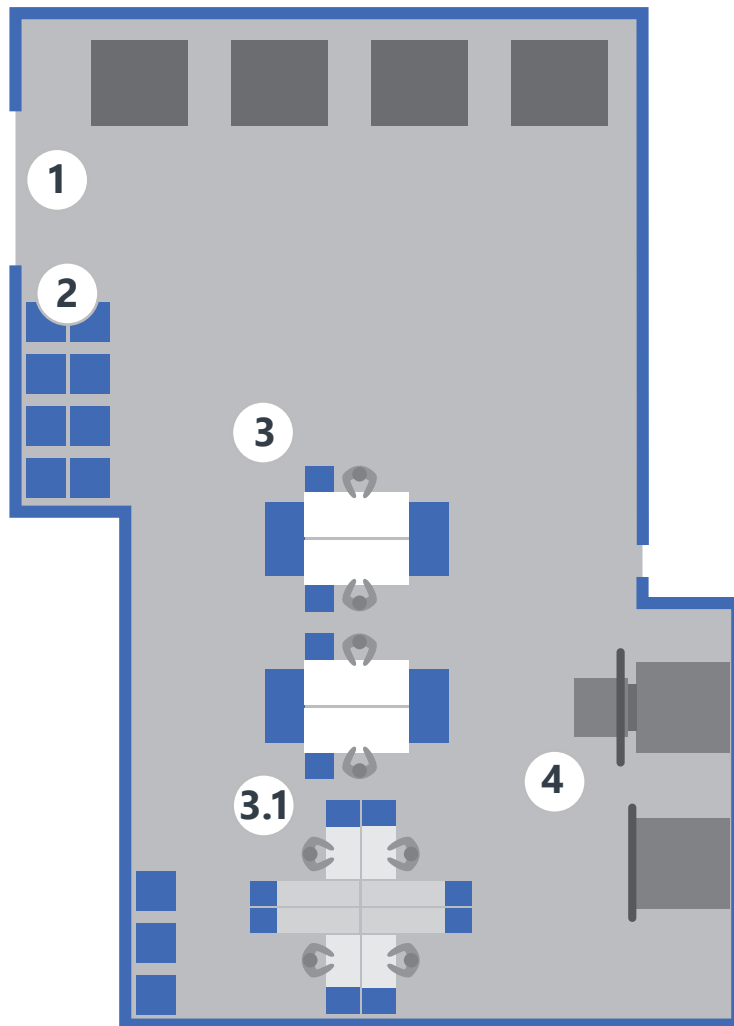
Clean garment delivery and soiled garment removal to the agreed schedule.

Quoted
Lead
Time

LAUNDRY FLOWCHART



LAUNDRY FLOWCHART | SOILED SIDE



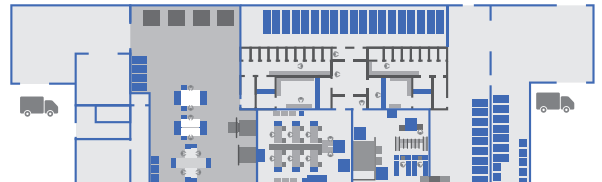
Controlled Environment

1. Soiled garments are received from the customer.
2. The garments are stored in Pre-Sort Trolleys.
3. The garments are 100% inspected and scanned into process batches.

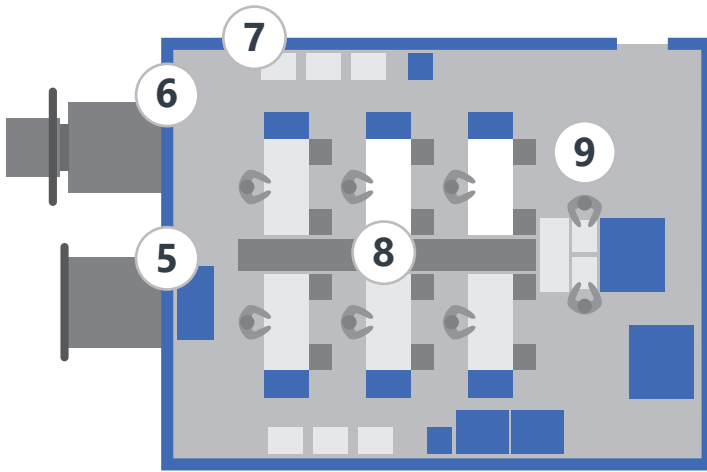
Optional

- 3.1. Damaged garments are re-directed to sewing/repair for validated repairs. Validated double repairs are recorded in ProTrack.
4. Process batches are placed into pre-wash trolleys.

All process control data is logged against the wash batch ensuring traceability.



LAUNDRY FLOWCHART | LAUNDRY



cGMP Grade C / ISO 14644 Class 5 Cleanroom

5. The wash batches are washed in a barrier washing machine.

Garments are processed through barrier washing machines incorporating authorised and validated wash programmes.

All programmes include a validated thermal disinfection cycle (typically 71 °C for five minutes) achieving a 5 Log reduction in garment bioburden.

The process is validated on SCADA using temperature time and water conductivity.

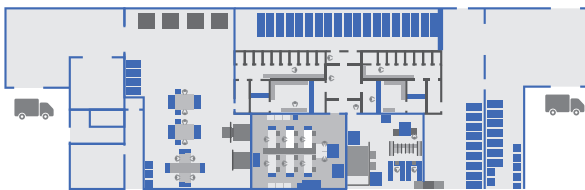
6. The garments are Tumble Dried and decontaminated in HEPA filtered air with the tumbling chamber pressure controlled to be mid-way between ambient and the cleanroom pressure.

The process is validated on SCADA using temperature and air pressure.

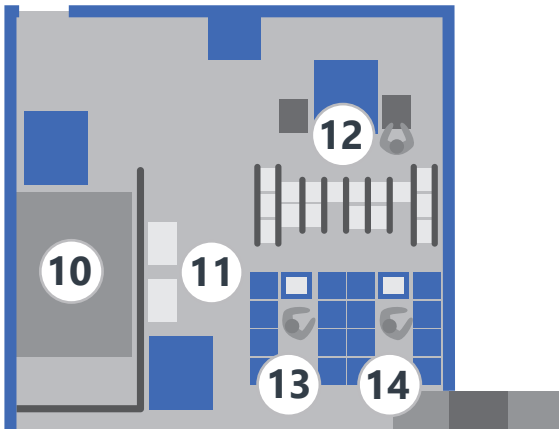
7. The dry garments are transferred into the cleanroom awaiting folding.

8. The garments are inspected, folded and placed into bags.

9. The garments are then sealed in autoclavable pouches whilst within the Class 5 Cleanroom environment



LAUNDRY FLOWCHART | AUTOCLAVE STERILISATION/ PACKING



cGMP Grade C / ISO 14644 Class 6 Cleanroom

10. The garments are autoclaved.

Terminal Sterilisation by Autoclave to ISO17665.

Validated sterilisation cycle achieving at least 134°C for 4 minutes.

The autoclave cycle is monitored by SCADA.

Optional

Garments not requiring sterilisation transit the autoclave on a pass through cycle.

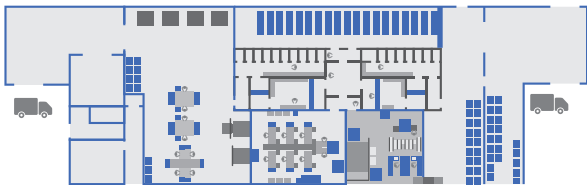
11. Dry garments are stored prior to secondary packing.

12. The batch number is printed onto the primary bag along with customisable information such as the garment type and size.

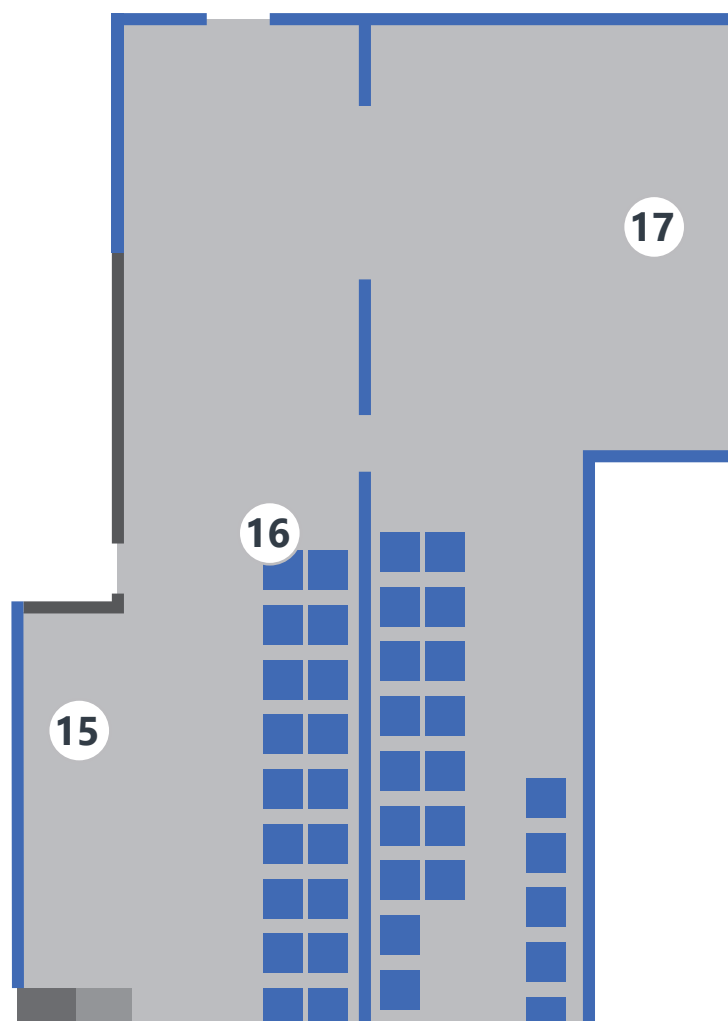
The garments are double or triple bagged according to customer requirements.

13. Garments are sorted on a semi-automated system using the RFID tag. Typically garments are sorted for a customer by product and size if used as pool stock or by locker number if wearer identified.

14. Garments are placed into outer protective bags.



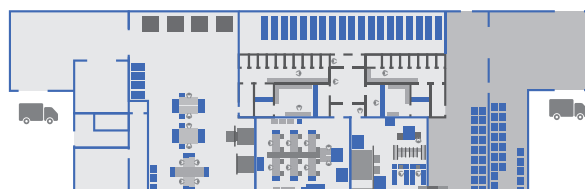
LAUNDRY FLOWCHART | DISTRIBUTION



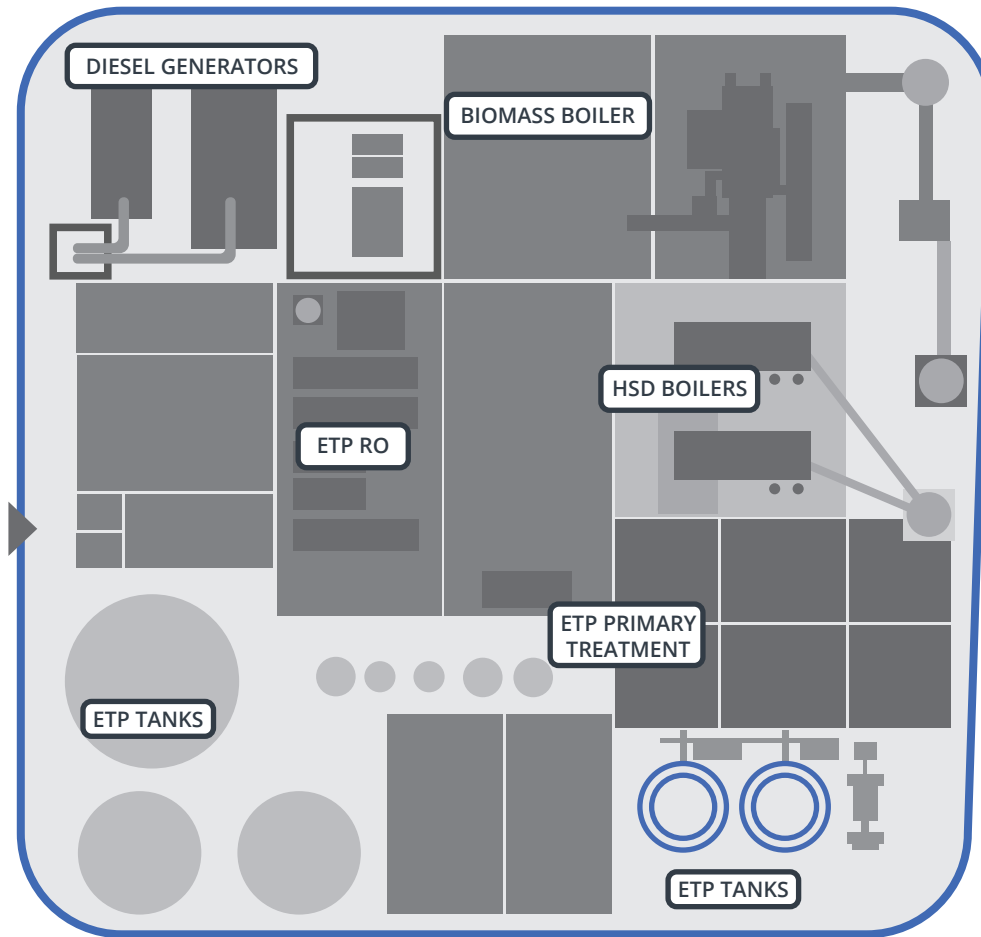
Controlled Environment

15. The garments in outer bags are placed in protective hampers for transportation.
16. The filled hampers are tracked into laundry cages.
17. The Laundry cages are dispatched on Micronclean vehicles direct to the customer.

Our system ensures full garment traceability up to the customer premises.



LAUNDRY FLOWCHART | UTILITIES BLOCK



Utilities Block

DUPLEX HSD BOILERS allow redundancy, particularly for maintenance / annual boiler inspection.

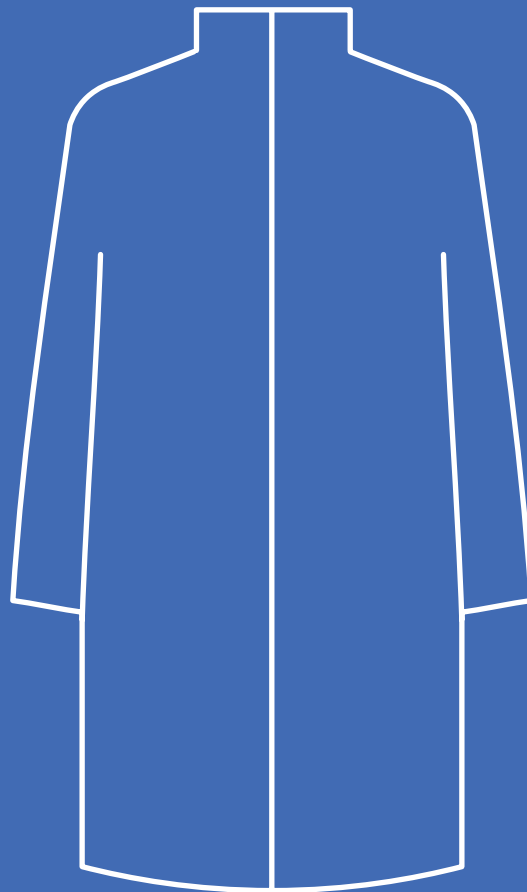
BIOMASS BOILER to be installed once the plant volumes have sufficiently increased. Biomass is a sustainable source of carbon reducing the plants impact on global warming.

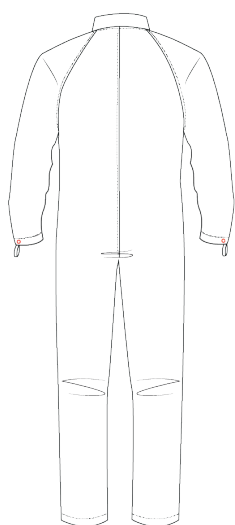
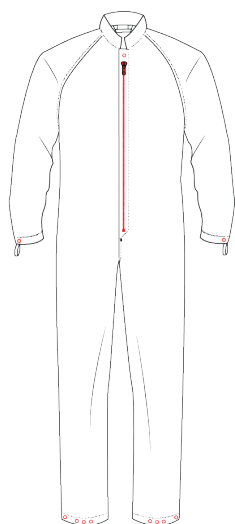
DIESEL GENERATORS provide continuity during power outages. All IT and equipment control systems are supported by full UPS.

EFFLUENT TREATMENT PLANT utilises effluent treatment technology, heat recovery followed by carbon filtration, ultrafiltration and a 6 stage RO process. The final process water will be $<30\mu\text{S}/\text{cm}$.



CLEANROOM GARMENTS





STANDARD CLEANROOM COVERALL



FEATURES

Integral RFID Transponder;
Suitable for autoclaving and gamma irradiation;
Centre front zip fastening coverall;
Stud adjustments at neck, wrist and ankles;
Raglan sleeves;
Mandarin collar;
Full cleanroom construction;
Heat sealed edges;
Seams are twin needle stitched.

FABRIC WEIGHT

110 gsm

COMPOSITION

98% Polyester/ 2% Antistatic

WEAVING STRUCTURE

3/2 twill
5mm grid

STD SIZE RANGE

SML - 2XL
Regular

NON-STD SIZE RANGE

3XS to 8XL
Regular

EXPECTED GARMENT LIFE

100 cycles

APPLICABLE STANDARDS

Validated fabric and garment design to
IEST RP CC0003



ESD type garment with Anti-Static
nature

STD COLOUR

 Light Blue



STANDARD CLEANROOM BOOT



FEATURES

Integral RFID Transponder;
Suitable for autoclaving and gamma irradiation;
Knee length overboot with flat sole;
Ankle tie tape adjustment which is secured to the heel;
Overfoot tie tape adjustment;
Stud adjustment on front of boot ;
Full cleanroom construction;
Heat sealed edges;
Seams are twin needle stitched.

FABRIC WEIGHT

110 gsm

COMPOSITION

98% Polyester/ 2% Antistatic

WEAVING STRUCTURE

3/2 twill
5mm grid

STD SIZE RANGE

XS - 3XL

EXPECTED GARMENT LIFE

100 cycles

APPLICABLE STANDARDS

Validated fabric and garment design to IEST RP CC0003



ESD type garment with Anti-Static nature

STD COLOUR



Light Blue



STANDARD CLEANROOM HOOD



FEATURES

Integral RFID Transponder;
Suitable for autoclaving and gamma irradiation;
Enclosed face design with single opening for eyes;
One size with popper adjustment for wearer comfort;
Full cleanroom construction;
Heat sealed edges;
Seams are twin needle stitched.

FABRIC WEIGHT

110 gsm

COMPOSITION

98% Polyester/ 2% Antistatic

WEAVING STRUCTURE

3/2 twill
5mm grid

STD SIZE RANGE

One Size

EXPECTED GARMENT LIFE

100 cycles

APPLICABLE STANDARDS

Validated fabric and garment design to IEST RP CC0003



ESD type garment with Anti-Static nature

STD COLOUR

 Light Blue



REUSABLE CLEANROOM SOCK

FEATURES

Integral RFID Transponder;
Designed Specifically for the Cleanroom Environment;
Padded soles for increased wearer comfort;
Colour coded sizing;
Technical fabric (COOLMAX ®) offering:

- Soft Material
- Cooling Performance
- High Levels of Breathability
- Moisture Wicking

FABRIC

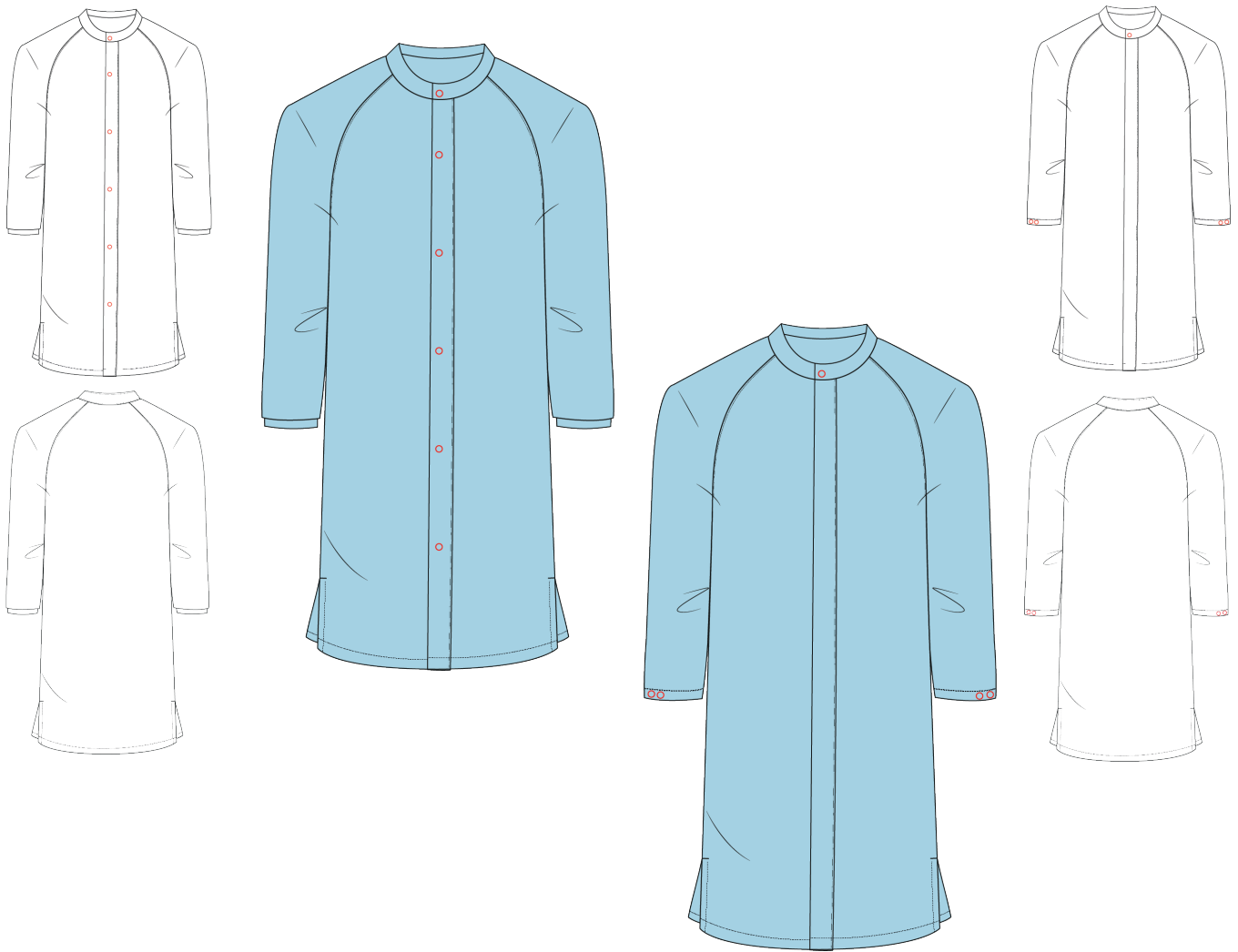
100% Synthetic Fabric

STD SIZE RANGE

Small, Medium and Large

STD COLOUR





EXTRA LONG COAT WITH ELASTICATED CUFF EXTRA LONG COAT WITH STUD CUFF



FEATURES

EXTRA LONG COAT WITH ELASTICATED CUFF
Integral RFID Transponder;
Relaxed 'tracksuit' fit;
Front neck closure with studs;
Front stud fastening;
Two side vents;
Elasticated bands at wrist;
No pocket.

EXTRA LONG COAT WITH STUD
Integral RFID Transponder;
Relaxed 'tracksuit' fit;
Front neck closure with studs;
Front stud fastening;
Two side vents;
Stud fastening at wrist;
No pocket.

COMPOSITION

98% Polyester/ 2% Antistatic

WEAVING STRUCTURE

3/2 twill
5mm grid

STD SIZE RANGE

XS to 3XL

EXPECTED GARMENT LIFE

100 cycles

APPLICABLE STANDARDS

Validated fabric and garment design to
IEST RP CC0003

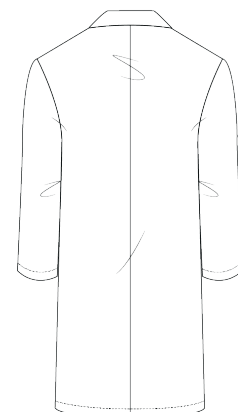
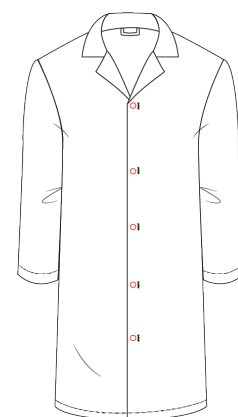
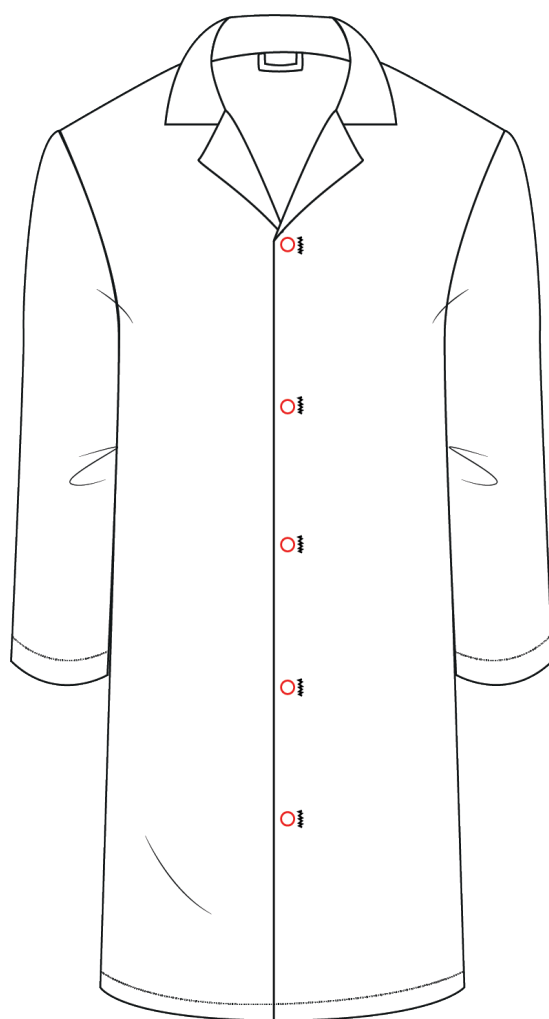


ESD type garment with Anti-Static
nature

STD COLOUR



Light Blue



LAB COAT

FEATURES

Integral RFID Transponder;
Regular traditional collar;
Two side vents;
Stud fastening at wrist;
Pockets optional.

COMPOSITION

65% Polycotton / 35% Polyester

STD SIZE RANGE

XS to 3XL

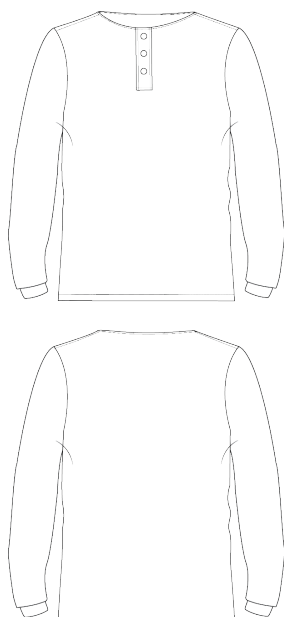
EXPECTED GARMENT LIFE

100 cycles

STD COLOUR



Light Blue



UNDERGARMENT TUNIC WITH ELASTICATED CUFF

FEATURES

Integral RFID Transponder;
 Polyester fabric Tunic with 3cm wide opening placket at front with exposed Stainless-Steel fastening (three studs);
 One-piece back;
 One-piece long sleeves with 5cm Polyester/Lycra cuffing;
 No pockets;
 Neck edge bound in self-fabric;
 9cm vents at both side seams;
 No collar;
 Twin needle Cleanroom seams.

FABRIC WEIGHT

94 gsm

COMPOSITION

99% Polyester/ 1% Antistatic

WEAVING STRUCTURE

Plain Weave

STD SIZE RANGE

XS - 2XL Regular

NON-STD SIZE RANGE

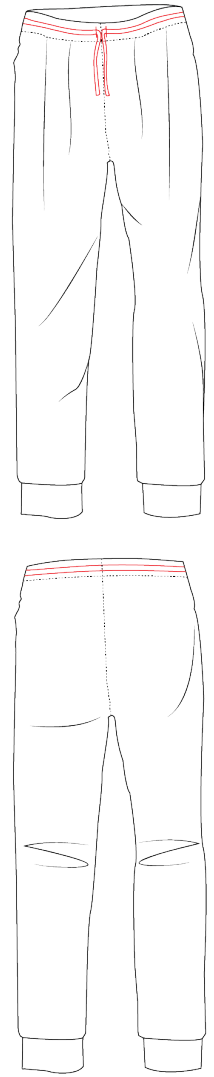
3XS to 6XL Regular

EXPECTED GARMENT LIFE

100 cycles

STD COLOUR

 Navy



UNDERGARMENT TROUSER WITH TIE WAIST

FEATURES

Integral RFID Transponder;
 Polyester fabric Under-trousers with two-piece legs;
 Polyester / lycra cuffing at ankles;
 Tape tie fastening at waist, secured with bartack at centre back of waist;
 Horizontal three-division accessory loop sewn to right leg seam as worn located 30cm down from top edge of waistband and centred over seam;
 :: 3cm division at centre, 2cm wide divisions at ends
 :: Finished length of 7cm
 No pockets;
 Twin needle Cleanroom seam.

FABRIC WEIGHT

94 gsm

COMPOSITION

99% Polyester/ 1% Antistatic

WEAVING STRUCTURE

Plain Weave

STD SIZE RANGE

XS - 2XL Regular

NON-STD SIZE RANGE

3XS to 6XL Regular

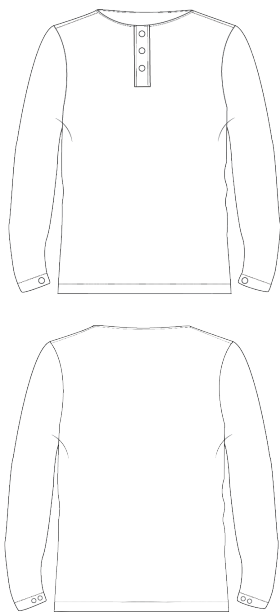
EXPECTED GARMENT LIFE

100 cycles

STD COLOUR



Navy



UNDERGARMENT TUNIC WITH STUD FASTENING AT WRIST

FEATURES

Integral RFID Transponder;
Relaxed 'tracksuit' fit;
Front neck closure with three studs;
Two side vents;
Stud fastening at wrist;
No pocket;
China collar;
Long wear life.

FABRIC WEIGHT

94 gsm

COMPOSITION

100% Polyester

WEAVING STRUCTURE

Plain Weave

STD SIZE RANGE

XS to 3XL

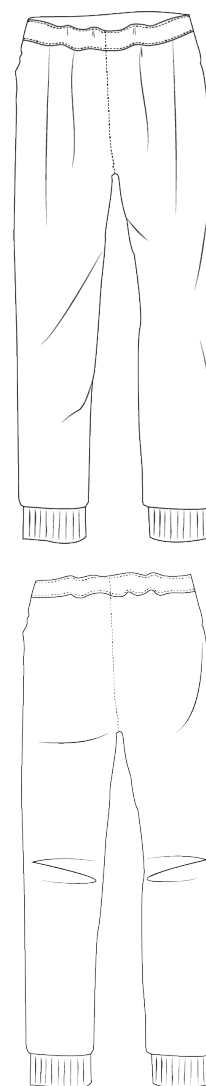
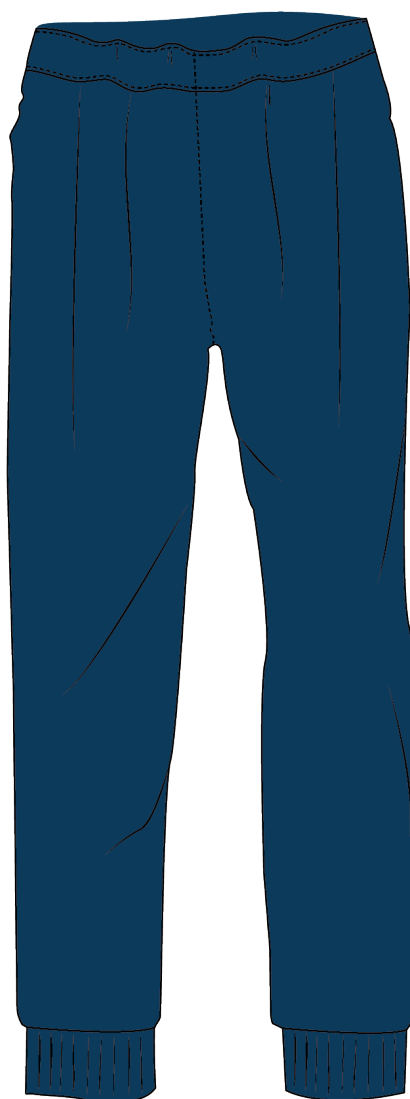
EXPECTED GARMENT LIFE

100 cycles

STD COLOUR



Navy



UNDERGARMENT TROUSER WITH ELASTICATED WAIST

FEATURES

Integral RFID Transponder;
Relaxed 'tracksuit' fit;
Elasticated bands at wrist with Lace ties;
No pocket.

FABRIC WEIGHT

94 gsm

COMPOSITION

100% Polyester

WEAVING STRUCTURE

Plain Weave

STD SIZE RANGE

XS to 3XL

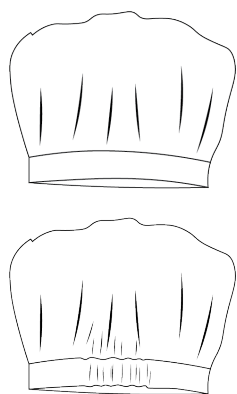
EXPECTED GARMENT LIFE

100 cycles

STD COLOUR



Navy



HAT

FEATURES

Integral RFID Transponder;
Plain coloured;
Elasticated back.

FABRIC WEIGHT

94 gsm

COMPOSITION

100% Polyester

EXPECTED GARMENT LIFE

100 cycles

STD COLOUR



Navy

CLEANROOM VALIDATION



CLEANROOM VALIDATION

MICRONCLEAN INDIA CERTIFICATION

Micronclean's India facilities and processes are professionally managed with external verification carried out by independent accreditation bodies.



NOTES

NOTES

NOTES



Micronclean India Pvt Ltd
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ICLB 08/2023

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