

PLANNING FOR ANNEX 1 WITH MICRONCLEAN



ANNEX 1

Annex 1 of EU GMP provides specific guidance on the manufacture of sterile medicinal product. The latest version of the guidance has been published and will come into force on August 25th, 2023.

This new version is substantially different to the previous version and includes additional guidance on cleaning and disinfection processes, alongside cleanroom clothing and eye coverings.



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.



4.33 TWO STAGE CLEANING AND DISINFECTION

Annex 1 states that for disinfection to be effective it must be a two-stage process. The first stage should be a process to remove surface contamination and the second stage should be disinfection.

As a result Micronclean would recommend that you use a Neutral Detergent which is formulated to work alongside your chosen disinfection regime.

Micronclean provide our Neutral Disinfectant, Delta, as a pre-saturated mopping solution to run alongside the our rotational disinfectants Alpha and Beta. Delta is also available in a variety of other pre-mixed formats including Trigger Sprays, Pre-Saturated Wipes and 5L RFU containers.

7.11 CLEANROOM CLOTHING

Within the UK, Micronclean is unique in that it has committed a large amount of resource to undertake fundamental research into its cleanroom fabrics. As a result we have qualified our cleanroom garments to prove how the properties of the fabric, and the garment, are affected by the numerous decontamination and sterilisation cycles.

Our garment study describes how we have tested a variety of cleanroom fabrics to assess the effect of both decontamination and sterilisation cycles (covering both irradiation and autoclave process) on several fundamental properties including particle filtration, durability, tensile strength and abrasion resistance. In this way we have established a unique knowledge about the right fabrics to use and the performance of our garment systems made from these fabrics.

As a result, when you are looking to qualify your garments in use, we can advise you on the use/life cycle of your garments, using a vast amount of research data, cutting your own qualification process considerably.

7.14 CLEANROOM SOCKS

Annex 1 states that cleanroom socks should be worn before entry into cleanrooms. As a consequence Micronclean would recommend that you use our Cleanroom Laundered Reusable Sock service.

This service offers:

- A naturally foot shaped sock made from 100% synthetic fibre which is available in three sizes.
- Full traceability from integral RFID chip.
- Decontamination in an ISO Class 4 GMP Grade B.
- Shipping alongside our existing cleanroom garment service.

If our laundered service is not suitable, we can offer a single size disposable cleanroom sock which is also sock shaped and manufactured from 100% synthetic fibre.

7.15 CLEANROOM GOGGLES

Annex 1 states that sterile eye coverings should be worn before entering a grade A or B cleanroom. As a result Micronclean would recommend that you use our Cleanroom Laundered Reusable Goggle service.

This service offers:

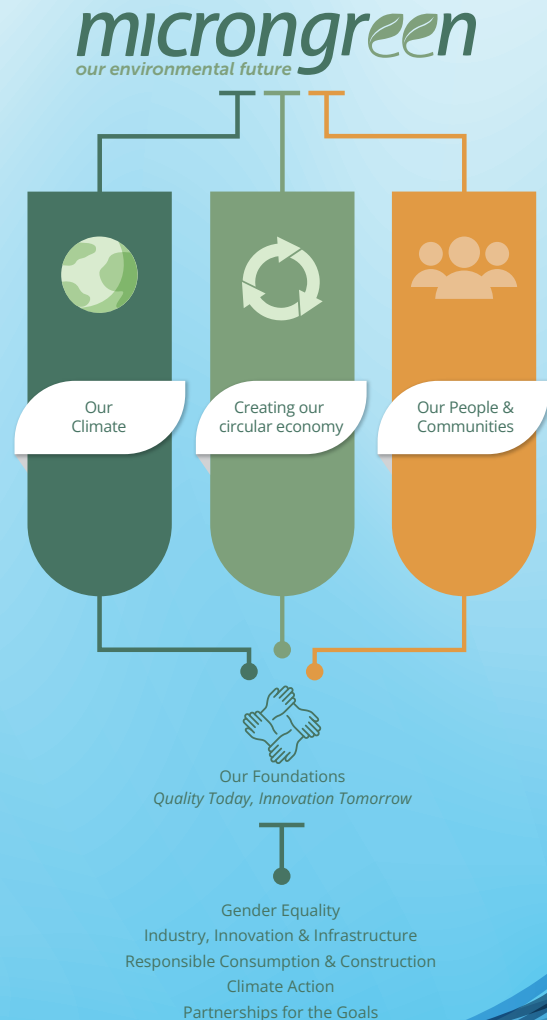
- Delivery of a lightweight, optically correct goggle, in a sterile ready to wear condition.
- Full Inspection of the goggle at the start of every decontamination cycle and full traceability.
- Decontamination in an ISO Class 4 GMP Grade B facility with the addition of an anti-fogging agent.
- Shipping alongside our existing cleanroom garment service.



“Our aim is to be the most sustainable specialist textile and cleanroom consumables business on the planet.”

Micronclean is committed to contributing to a sustainable future based on the three pillars of:

- Protecting our climate
- Creating our circular economy
- Delivering a positive impact for our people and communities



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