



FAQs

STERILE CLEANROOM GOGGLE

Q1: What is driving the requirement for me to use Cleanroom Goggles?

The requirement to use Cleanroom Goggles is being driven by the proposals in GMP Annex 1, which currently states that:

".... a sterile face mask and sterile eye coverings should be worn to cover all facial skin...."

Q2: What are your Cleanroom Goggles made of?

The Cleanroom Goggles have three main parts these being the lens, the body and the strap.

Component	Element	Material
Goggle	Lens	Co-polyester resin
Goggle	Body	Polypropylene/ dynamically vulcanised EPDM rubber
Strap	Knitted Insert Elastic (covered by)	Semi-dull polyester 26 gauge rubber
Strap	Cleanroom Fabric	99% high density polyester 1% Carbon

Q3: How are the Cleanroom Goggles decontaminated and are they provided Sterile?

The Cleanroom Goggles are decontaminated in our ISO Class 4/GMP Grade B facility using a dedicated wash programme and a Patent Applied for process, that is specifically tailored to the Cleanroom Goggle. The Cleanroom Goggles are then dried using a validated tumble during cycle to ensure that all residual moisture has been removed. Cleanroom Goggles are packed, then sent for Terminal Sterilisation using Gamma Irradiation (min. 25 kGy).

Q4: How are they packaged?

After drying, the Cleanroom Goggles are individually packed in a hermetically sealed polythene bag, then secondary bagged. The Goggles are then placed into a dedicated shipper box (one of 3 sizes) for transport to the Terminal Sterilisation facility and in turn the customers site.

Goggles per box	Size of the box
6	280 x 159 x 190
12	280 x 159 x 381
30	320 x 273 x 381

Cleanroom Goggles should be returned to us in the dedicated shipper box to help us lessen the environmental impact of shipping and mitigate the crush risk.

Q5: Do the Cleanroom Goggles come double bagged and do I have to pay extra for the double bagging?

Goggles are provided double bagged at no extra costs.

Q6: Can I wear my glasses?

The Micronclean Goggle is designed to be worn over prescription glasses in a cleanroom environment and should not cause any issues.

Q7: Can they be autoclaved?

No, these goggles are not design to be autoclaved.

Q8: How long do they last?

At present, the Micronclean Cleanroom Goggle has been validated to give a minimum in-service life of 10 cycles.

Q9: How long can they be used in the cleanroom?

A lot this will depend on your internal procedures and SOPs. Micronclean however recommend that the Cleanroom Goggle be used sessionally.

Q10: Should the change frequency be the same as garments?

Yes, they work in the same way as a cleanroom garment contract with a similar change ratio. The exact contract ratio will be discussed with both yourselves and Micronclean prior to quotation. In this way when the contract goes ahead the Cleanroom Goggles contract will match with your working schedules and our processing capability. Typically, this will be 5 changes to 11 issued.

Q11: Do Micronclean Sterile Cleanroom Goggles offer eye protection?

Micronclean Sterile Cleanroom Goggles are not intended or designed to offer any specific eye protection, EN 166 is therefore not relevant for this product.

Q12: What causes Goggle fogging?

Cleanroom Goggle lenses can fog, in a similar way to a car windscreen, due to condensation of water from the air onto the lens surface. Perspiration from the goggle wearer creates warm, humid air. When this air comes into contact with the cooler Cleanroom Goggle lens, moisture can be deposited. Due to surface tension, water accumulates as small droplets on the lens surface, and this is seen as 'fog'.

Q13: What do Micronclean do to mitigate goggle fogging?

The Micronclean sterile goggle is designed with indirect vent holes, which equalise the temperature inside and outside the goggle. There, are located: 6 vents on top: 4 middle vents 4mm wide, 2 outside vents 3mm wide, 4 bottom vents 1mm wide. In addition, Micronclean adds a unique anti-fog chemical treatment to the goggle lens surface during routine processing. This chemical acts to reduce the surface tension of water. With the chemical added, any water that condenses onto the lens surface sits as a

thin film (rather than droplets) and therefore reduce a fogging effect.

This treatment does not affect the goggle life or the sterility of the goggle.

Q14: What can I do to mitigate goggle fogging?

Micronclean recommends the following practices to customers:

- Store the goggles at the same temperature as the environment in which they will be used. This will help to minimise temperature differences between the environment and the goggle lens, which should reduce the fogging effect. If your controlled environment is cold, store goggles at ambient temperature, closer to the wearer's body temperature.
- Ensure that the vents on the Cleanroom Goggle shroud are not blocked or covered when goggles are worn. The vents help to equalise temperatures inside and outside the goggle, which will reduce the fogging effect.
- When Cleanroom Goggles are first donned, it can take some time for the temperature of the Cleanroom Goggle to equalise with the temperatures of the wearer and the environment. Immediately after donning, goggles are therefore at highest risk of fogging. Any fogging can then clear over a period of time. Immediately after donning goggles, wearers should therefore use the goggles as normal and be patient.

Q15: What is Particulate Release for the Goggles?

Particle release from the Micronclean Cleanroom Goggle is in line with the ASTM F51/00 Class A classification.

Q16: Do we comply with any Quality Assurance?

Product supplied under BS EN ISO 9001:2015 registered systems.

Q17: What is the Shelf Life for the Goggles?

Shelf life for the Goggles is 12 months from date of manufacture.

