



## CE DOCUMENTATION REVIEW

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**Review Goal :** Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Medical Devices Directive Annex VII.

**Products:** Disposable protective clear shields with elastical head bands, no sterile.

**Models :** 320x 400 mm, 180° full protection and isolation, high light transmittance.

**Classification:** Class 1 (non sterile). The shields are Category 1 PPE products and are self-certified CE Marked.

**Review Output:** We attest that the Technical information on file in reference to the Directive 93/42/EEC Medical Devices Directive Annex VII is in place for the CE Marking Process. This document is issued on a voluntary basis whereas the manufacturer is responsible to carry out all the necessary as required in the directive.

### **Manufacturing of Disposable protective clear shields with elastical head bands, no sterile:**

Please note that when manufacturing the face shields we act as if infected by the COVID-19 virus. We wear a face mask and a fresh pair of gloves when collecting each batch of parts. We store the parts immediately in a sealable bag.

We store the packed face shields and wait for for 2-3 days before distributing them to reduce risk of transmission.

We do not store the entire stock in one place to minimise the risk of cross contamination.

The laser cut face shield is designed as an easy-to-use PET face shield for healthcare staff and essential key workers.

The face shields consist of an adjustable head strap.

The face shields are manufactured by laser cutting techniques and are made from a thermoplastic called polyethylene terephthalate (PET).

The shields are Category 1 PPE products and are self-certified CE Marked.

### **Decontamination: Cleaning your face shield**

Disinfection (the process of eliminating or reducing harmful microorganisms) and sterilisation (the process of killing all microorganisms )are both acceptable to decontaminating of the face shield.

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### How to clean the face shield

**WARNING:** Before you apply any disinfection solution, we advise to try it first near one edge of the visor and inspect whether the solution cause damage to the surface of the visor.

Face shields can be cleaned by regular cleaners, sanitizers and alcohol wet wipes. Workplaces can use the professional sterilising equipment to decontaminate the face shields.

It is recommended to sink the shield parts into disinfection solutions for best practice, this will ensure the solution reaches 100% of the visor surface. You can also use aerosol (spray) at least twice to reach most of the surface, for best practice.

Most of the solutions evaporate after several minutes. You can remove the remains using a paper towel, throw away surface cleaners. Avoid using the same towel on multiple shields, avoid cross-contamination and always wipe in one direction.

### Recommended methods of decontamination

METHOD	CONDITIONS	TIME	EFFECTIVE AGAINST
Autoclave (cold)	56-60°C	60 minutes	Bacteria, viruses
Isopropyl alcohol	70-75%	5+ minutes	Bacteria, viruses
Ethanol	> 70%	5+ minutes	Bacteria, viruses
Descogen®-S (granules)	1.5%	30 minutes	Bacteria, viruses
Sodium Hypochlorite (Savo)	0.01%-0.5%	5+ minutes	Bacteria, viruses
IPA steam (70%, 30% water)	45-65°C	30-90 minutes	Bacteria, viruses
PVP-I (iodine disinfection)	4%	5+ minutes	Bacteria, viruses
Hydrogen Peroxide	6-25%	5+ minutes	Bacteria, viruses
Soap water	Repeated washing	5+ minutes	Bacteria, viruses
Ozone	Strong oxidising effects	Varies	Bacteria, viruses
Gamma radiation	Strong ionizing radiation	Varies	Bacteria, viruses
UV-C	Radiation	Varies	Bacteria, viruses

The method of high temperature 120°C and over is tested and evaluated as not ideal for the decontamination process, because of structural damage to the shield as PET material deforms under high temperature

Please **dispose** the plastic face shield in non-recycled plastic waste.

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