

**PRODUCT DESCRIPTION:**

Face visors are personal protective equipment devices that are used for protection of the facial area and associated mucous membranes (eyes, nose, mouth) from splashes, sprays, and spatter of body fluids. Face visors provide a barrier to acutely-expelled aerosols of body fluids and protect a large area of the face.

This protective Face Visor is manufactured for COVID-protection only. This protective Face Visor is not a PPE device for general use and shall not be used for purposes other than protection against COVID-19.

INTENDED USE:

The Reusable Innovia Face Visor is intended to provide top, side, and front face protection from aerosols and to minimise airborne cross-contamination.

WARNINGS AND PRECAUTIONS:

- **THIS PRODUCT CAN BE RE-USED BUT SHALL NOT BE USED FOR MORE THAN FIVE SHIFTS**
- **DO NOT RE-USE OR RE-STERILIZE THIS DEVICE FOLLOWING THE SPECIFIED FIVE SHIFT PRODUCT LIFE CYCLE**
- This device is supplied clean but is **NON-STERILE**. The instructions on cleaning the device provided below should be followed prior to use.
- It is recommended that this device is used as part of a PPE regimen
- Care should be taken when putting on and taking off the device to prevent contamination.
- Care should be taken if it is necessary to adjust the visor during use, as this may lead to contamination.
- The use of a face visor in combination with goggles can lead to poor peripheral vision. Care should be taken when selecting goggles to ensure that vision is not adversely affected, when used in combination.
- Always remember that no item of PPE can provide full protection and care must always be taken while carrying out the risk related activity.
- Ensure that the visor conforms to the face/head and that the visor does not slip whilst in use.
- Check before use that the visor will not become detached from the headband.
- It is generally recommended that for added protection (and depending upon circumstances), PPE should be worn by HCP on entry into patient rooms or care areas.
- After use, the visor should be carefully removed without contaminating the eyes, mucous membranes or clothing with potentially infectious materials and discarded.
- The product comes into contact with bodily fluids, which can be contaminated. Care should be taken in the handling and disposal of the device after the specified five shift product life cycle to prevent contamination.
- Dispose of this device after use in accordance with standard hospital protocol
- Warning — Parts of the visor that come into contact with your skin may lead to allergic reactions. In this case please discontinue use and seek medical device
- To optimise protection, it will be necessary to use these products with suitable gloves/gowns/masks. In this case, before carrying out the risk-related activity, consult your supplier or supervisor to ensure that all your protective products are compatible and suitable for your application

Considerations prior to use & Storage

1. Limited-use devices have not been validated for re-use outside of the specified product life cycle.
2. Dispose Face Shield after 5 uses. If the visor becomes scratched or damaged before then, it should be replaced immediately
3. If the visor becomes damaged it will NOT provide the optimum level of protection, and therefore should be replaced immediately
4. Never use this visor for protection against other hazards outside of it's intended use.
5. When not in use, store the visor within the sealable bag after following the instructions overleaf. Avoid excessive folding. If product is wet, allow it to fully dry before placing into storage
6. Store the product in a dark place, out of sunlight, when not in use

INCIDENT REPORTING:

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

MANUFACTURED BY:

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READ INSTRUCTIONS BEFORE USE


INSTRUCTIONS FOR USE:

Following cleaning follow hospital approved protocol for putting the device on in conjunction with other PPE.

Put on the visor, taking care to ensure that it is secure and correctly fitted.

To remove, handle via the head band. The visor should be carefully removed without contaminating the eyes, mucous membranes or clothing with potentially infectious materials and discarded.

SHELF LIFE:

Recommended maximum shelf life is 3 years. Device should be disposed with medical waste in accordance to facility or institutional guidelines /procedures.

CLEANING:









This device is supplied non-sterile and should be wiped down with an anti-bacterial wipe and/or denatured ethanol prior to each use. See instructions overleaf.

CLASSIFICATION:

This product is classed as Category III Personal Protective Equipment (PPE) by the European PPE Regulation (EU) 2016/425 and have been shown to comply with this Regulation through limited testing against the Harmonised European Standard EN166:2001. These products have been tested in accordance with EN166:2001 Clauses:

- **6:** Design
- **7.1.1:** Field of Vision
- **7.1.2.1:** Retractive powers
- **7.1.2.2:** Transmittance
- **7.1.2.3:** Diffusion of light
- **7.1.3:** Quality of materials
- **7.1.5.1:** Stability at elevated temperature
- **7.1.7:** Resistance to ignition
- **7.2.4:** Droplets and splashes of liquid
- **7.3.2:** Resistance to fogging

GRAPHICAL SYMBOLS USE ON LABELLING:

Lot Number	Consult Instructions for Use	Catalogue Number	Non-sterile	Manufacturer	Date of Manufacture	Caution	Do not use if product is opened or damaged and consult instructions for use
							

HAZARDS ASSOCIATED WITH THE RE-USE OF LIMITED-USE DEVICES:

1. Limited-use devices have not been validated for re-use outside of the specified product life cycle.
2. If you re-use a limited-use device you may be held Legally Liable for the safe performance.
3. Cross-contamination and infection risks to patients. Including transmission of:
4. Device failure through material fatigue or degradation caused by use and design:
5. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.
6. Materials may degrade, becoming unacceptable when compared to original manufacturing criteria
7. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.

THIS PRODUCT MEETS THE FOLLOWING:

Regulation (EU) 2016/425 of the European Parliament and of the Council
 Harmonised European standard EN 166:2001

Declaration of conformity can be accessed on the manufacturer's website (see details below)

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DONNING THE CM-5001R REUSABLE INNOVIA FACE VISOR



1. Remove the CM-5001R Reusable Innovia Face Visor from the supplied resealable bag.



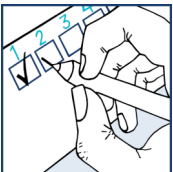
2. Use a Clinell[®], IMS 70/30 or similar antibacterial wipe to clean the reverse side of the visor making sure to clean the foam head support. For optimum results a dry wipe down is recommended following use of antibacterial cleaning.



3. Clean the front of the visor screen using a Clinell[®], IMS 70/30 or similar antibacterial wipe. For optimum results a dry wipe down is recommended following use of antibacterial cleaning.



4. Use the white space at the top of the visor to personalise as shown .

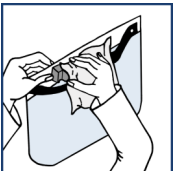


5. Track the number of uses by ticking the boxes at the top of the visor at the start of each shift. Pull the elastic headband and slip over your head ensuring that the foam headrest sits securely on your forehead

DOFFING THE CM-5001R REUSABLE INNOVIA FACE VISOR



1. Clean the front of the visor screen using a Clinell[®] or similar antibacterial wipe. For optimum results a dry wipe down is recommended following use of antibacterial cleaning.



2. Use a Clinell[®] or similar antibacterial wipe to clean the reverse side of the visor making sure to clean the foam head support. For optimum results a dry wipe down is recommended following use of antibacterial



3. Place the CM-5001R Reusable Innovia Face Visor back within the supplied bag and reseal the bag.