

## Innovia Face Shield Specification Sheet (SUMMIT Medical Manufactured Version)



### Product Overview

- Designed to provide face protection from aerosols and minimise airborne cross-contamination
- CE marked to regulation 2016/425 (Notified Body BSI Netherlands Group BV)
- Meets all applicable requirements of EN 166:2002 Personal eye Protection
- Provides top, side, and front face protection for the healthcare professional
- Elastic headband provides secure retention and easy application
- 22.8cm long screen provides maximum protection
- Can be worn over prescription eyewear and facemasks
- Anti-fog and optically clear screen for maximum visibility
- Lightweight and comfortable
- Latex free
- Non-sterile, single use

Description	Pack Size	Box Size	Code
Innovia Face Shield	1x Visor	100x Packs	CM-5001

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### Material Specification

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#### Product Component

#### Specification

Supportive Headrest	Polyurethane Foam
Visor	Clear PET (Polyester), 230 X 330 X 0.3 mm
Headband	Latex free elastic
Packaging	Poly Bag
Outer Box/Carton Packaging	Plain Brown, Single Wall (xx)

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### Intended Use

The device is intended to provide top side and front face protection from splashes and sprays of bodily fluids and to minimise cross-contamination.

### Instructions for Use

- This device is intended for SINGLE USE ONLY. It is not intended for repeat use.
- Care should be taken when putting on and taking off the device to prevent contamination.
- Care should be taken in the handling and disposal the Innovia face visor after use to prevent contamination.
- Face shields should not be used as a form of respiratory protection.
- PPE must not be adjusted during patient care, as this may lead to contamination.

### Conformity to the European Directives

The device is class I rule 1 of the 93/42/EEC Medical Devices Directive (MDD) amended by 2007/47/EC.