



## G Performance obtained in technical examinations to verify the levels or classes of protection of PPE

For analysis of the compliance of this PPE with the Essential Health and Safety Requirements, reference was made to the European Standard EN166:2001 - Personal Eye Protection.

In particular:

- General construction
- Field of view
- Optical requirements
- Quality of material and surface
- Increased robustness
- Resistance to aging
- Protection against droplets and liquid splashes

## H Replacements

This PPE is designed to be used only with Vista-Tec ilGrande replacements.

Product REF	Name	Description
5663	Vista-Tec ilGrande	1 frame, 2 shields, 1 headband
5666	Vista-Tec ilGrande shields	5 shields

## I Marking

The CE marking affixed to the PPE states the compliance of the product with Regulation (EU) 2016/425 and with the technical standard EN 166:2001. The identification of the production batch is clearly shown on the packaging by the initials LOT.

### Frame marking

Identification Polydentia	
Harmonized standard applied	EN166
Field of use: liquids	3
Increased robustness	S
Certification mark	CE

### Face shield marking

Identification Polydentia	
Optical class	1
Increased robustness	S

## J Declaration of Conformity

The Declaration of Conformity is available on the website [polydentia.ch](http://polydentia.ch)

## K Notified Body

Italcert Srl (NB 0426)  
Viale Sarca, 336  
20126 Milano - Italia



for more  
information



### Polydentia SA

via Cantonale 47 • 6805 Mezzovico-Vira • Switzerland  
Phone +41 91 946 29 48 • Fax +41 91 946 32 03  
[polydentia.ch](http://polydentia.ch) • [info@polydentia.ch](mailto:info@polydentia.ch)

Made in Switzerland

Personal  
protective  
equipment  
REV 03 10.2020



EN 166:2001



# Instruction for use

# Vista-Tec ilGrande

The extended protection



swiss manufacture



## A Description and field of application

Vista-Tec ilGrande is an EN166:2001 certified face shield for protection against liquid splashes.

Vista-Tec ilGrande can be used in dental, outpatient, hospital, laboratory or other professional settings that require similar protection.

The face shields, made of polycarbonate, are resistant and do not yellow when exposed to light. They are reusable and easy to clean (see Paragraph E).

Vista-Tec ilGrande is comfortable and light (about 42g), it can be worn comfortably for long periods as it does not create distortions and visual fatigue, also ensuring a wide field of vision.

The protective face shields are easily attached through the clips integrated into the frame.

Vista-Tec ilGrande adapts stably to any type of face thanks to the headband.

Can be used with surgical masks.

This Personal Protective Equipment (PPE) is classified, according to Annex I of EU Regulation 2016/425, as Category II Protective Equipment.

## B Composition

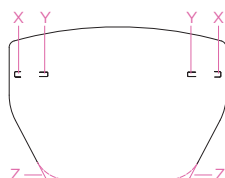
**Frame Vista-Tec ilGrande:** Polysulfone

**Headband:** Silicone

**Transparent protective shield:** Polycarbonate

## C Assembly

**1** Remove the protective film on both sides by the corners Z. The protective shield has two pairs of openings, X and Y. The openings called X act as a support into which the temples of the frame will be inserted, while the openings Y are the attachment points of the clips present on the frame.



**2** Insert the right temple arm of the frame into hole X on the right side of the shield; slide the shield onto the frame up to the clip. Wrap the shield on the frame and insert the left temple arm in the second hole X on the left side of the shield.



**3** Insert the protective shield into the fixing clip on the frame. Slide the shield into the retaining clip until it locks in place. Repeat the operations for fixing the left side of the protective shield.



**4** Fix the two silicone bands on the specific supports at the end of the temple arms of the frame.



**5** The width of the band can be adjusted by pulling the ends.



**6** Picture of the device correctly assembled.



## D Warnings

Vista-Tec ilGrande does not prevent the contagion of diseases or infections but reduces the risk of coming into contact with liquid splashes aimed at the eyes, nose and mouth.

This PPE can only be used in dental, outpatient, hospital, laboratory or other professional contexts that require similar protection where the user can directly evaluate the effectiveness against non-serious risks. The PPE must not be used in case of risks that could lead to death or irreversible damage. In case of doubt regarding the effectiveness against risks that are difficult to assess, the user must NOT use the PPE.

This PPE is not designed to protect the user from violent impacts against any obstacles; if ophthalmic glasses are worn, this PPE can transmit the impact.

The PPE does not protect from sunlight, UV radiation, laser and BLUE light (used in photopolymerization in the dental field). Do not expose the PPE to sunlight or UV lamps for long periods.

The materials constituting the PPE, in contact with the skin, can cause allergic reactions in people sensitive to these types of materials (see Paragraph B).

The user is responsible for determining the suitability of the Vista-Tec ilGrande for the intended use.

Avoid exposing the PPE to chemicals, fumes, vapors or heat sources. Do not use solvents or organic liquids such as petrol in contact with the PPE.

Scratched or damaged shields must be replaced.

As reported in paragraph 10, point P, of the EN166:2001 standard, if protection from high speed particles at extreme temperatures is required, the face shields must be marked with the letter T immediately after the impact letter, i.e. FT, BT or AT. If the impact letter is not followed by the letter T, the eye protector should only be used as protection from high speed particles at room temperature.

## E Indications for proper cleaning and maintenance

### Cleaning

It is advisable to remove the shield from the frame for cleaning.

Protective face shields must be cleaned regularly after each use using warm water and neutral detergent. Use soft microfibre cloths to dry the components.

The polycarbonate shields are characterized by high optical performance, so please pay special attention when cleaning. The presence of particulate matter can cause scratches on the shield.

Surface disinfection of the frame and face shields Vista-Tec ilGrande can be carried out using alcohol-based products. Never immerse the components completely in disinfectant solutions. Please always refer to the disinfectant manufacturer's instructions.

The frame and headband can be sterilized in an autoclave (up to 134 °C).

WARNING: Do not autoclave the face shield.

### Maintenance

The PPE is designed to be reused multiple times if kept in good condition. It can be used for 3 years from its first use.

Do not use the PPE if there are evident marks on the protective shield or if the frame is damaged.

Replace the damaged components if necessary.

## F Information for storage and transport

Store in a clean and dry place, away from sunlight and in an environment free of organic vapors. Vista-Tec ilGrande must be transported and stored in its original packaging, at a temperature between +5 °C and +30 °C.