



Xiamen Winner Medical Co., Ltd.
CE Technical Documentation

Doc. No.: IFU-28

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Doc. Name:

Instruction for Use

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According to Regulation (EU) 2017/745 Annex II and III

CPR Face Shield

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Instruction for Use

Product Name:

CPR Face Shield

Product Description:

The CPR face shield is a first aid tool, intended to provide first aid and help during cardiopulmonary resuscitation (CPR). The product is designed as a one-way valve, which can avoid direct contact with the mouth, nose and face of the patient. The mask can block the liquid and secretion produced by the patient during the first aid, and play a barrier role in the isolation of the rescue personnel and the patient.

Production Specification:

Product Type	Product Size	One-way valve diameter	Packing Size	Weight
TW8340H-R	280×205 mm	230 mm (Diameter of outer cover) 20 mm (Diameter of inner cover)	5x5.5cm (Nylon Bag or PP Box) (1000pcs/carton)	11.37g (Nylon Bag) 12.8g (PP Box)

Intended purpose

The CPR face shield is intended to provide protection during cardiopulmonary resuscitation (CPR) by preventing cross-infection between the rescuer and the casualties.

Indications

The CPR face shield is intended to provide protection during cardiopulmonary resuscitation (CPR) by preventing cross-infection between the rescuer and the casualties.

The product has no specific indications.

Intended users

Rescuers for outdoor and training and teaching centers.

Intended patient population

The casualties in need of first-aid.

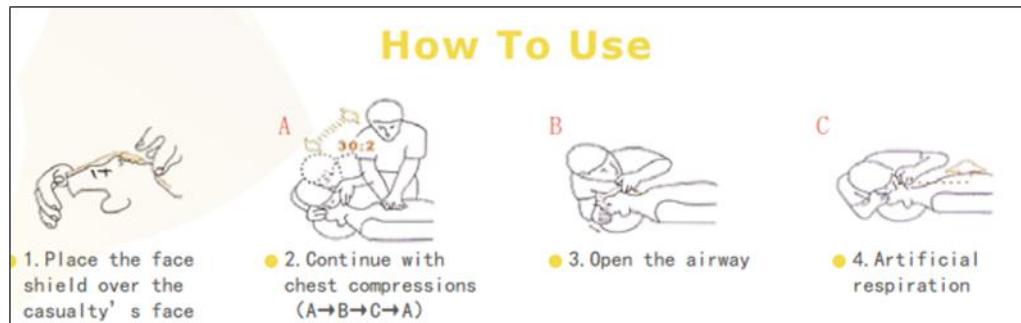
The combination of the device with product

The CPR Face Shield is not intended for combination use with other products.

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1. Place the face shield over the casualty's face.
2. Continue with chest compressions.
3. Open the airway.
4. Artificial respiration.



Cautions



- The CPR face shield needs to be placed flat on the patient's mouth and nose in order to effectively rescue the patient.
- Please replace the new product if the CPR face shield is broken, cracked, or any damage occurs. Use immediately after unpack.

Shelf life

Five years from end of manufacturing.

Contraindication

The casualty's face is in severely injured or has obvious deformities. It might affect the correct position of mask placed and ineffective exhale from rescuers to patient.

Disclosure of residual risks

The product may contain the following residual risks:

- Bacterial or virus infection to the patient or healthcare professional
- Allergies and irritation

Storage and Transportation

- a. Product should be stored in a dry, ventilated environment, away from fire sources and flammable materials.
- b. It should be protected from heavy pressure, direct sunlight and rain and snow.
- c. The Storage condition should be at room temperature.

Symbol

	Manufacturer		CE mark
	Authorised Representative in the European community		Unique Device Identification
	Importer		Batch code
	Medical Devices		Date of manufacture, made in China
	Caution		Use by
	Consult instructions for use		Keep dry
	Do not reuse		Keep away from sunlight
	Non-sterile		Keep upright during transport
	Catalogue number		

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Incident Reporting

The user and/or patient shall report any serious incident that has occurred in relation to the device to Xiamen Winner Medical Co., Ltd. and the competent authority of the EU Member State in which the user and/or patient is established.



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