Instruction for Use

CE

Product Name:
Resuscitation Mask

Product Description
It is made up of a PVC mask (including the mask, one-way valve, elastic strap, and accessories: gloves). This product is mainly used to perform artificial respiration on patients, helping them maintain normal breathing before they regain consciousness in the short term. It is a simple tool for artificial ventilation. Compared with mouth-to-mouth ventilation, it can effectively prevent direct contact between medical personnel and patients, avoiding cross-infection. It can replace mouth-to-mouth breathing. It does not require an electric device and is convenient to carry.

Production Specification:

Product Type	Content	Length	Width	Height	Cavity Volume
TW8340/TW8340N	Mask	130±20mm	100±20mm	85±20mm	170±20mm
TW8341/TW8341N	Mask, PVC gloves				
TW8342/TW8342N	Mask				
TW8343/TW8343N	Mask, PVC gloves				

Principle of Operation
It provides auxiliary artificial respiration to patients through a mouth-to-mask one-way valve ventilation. It is easy and quick to use. The rescuer blows air through the one-way valve into the patient's mouth. During the patient's expiration, the rescuer removes their mouth from the valve. The respiration resistance is very low.

Intended Purpose
The Resuscitation Mask is intended for mouth-to-mask ventilation of non-breathing patients. It is designed to blow air into patients and isolate emergency personnel from the victim's mouth to prevent cross-infection. The mask is a non-sterile product for single-patient use.

Indications
The product has no specific indications.

Intended Users
The product shall be used by qualified and trained medical staff.

Intended Patient Population
All populations.

The combination of the device with product
The Resuscitation Mask (if with gas port) is intended for combination use with oxygen bag only.

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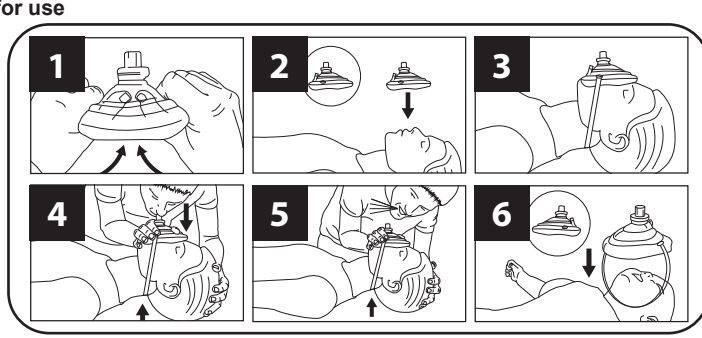

1.Put on protective gloves if available. Check that the filter is firmly in place and unfold the mask.
2.For adults and pediatrics: Place the rim of the mask between the lower lip and chin. Position the "nose" over the nose.
3. Fix the mask with the rubber band behind the head. Stretch the patient's head.
4. Seal as illustrated and blow slowly into the one-way valve until the chest rises.
5. Remove your mouth and allow the patient to exhale. Repeat as per CPR guidelines.
6. For infants: Reverse the mask direction, so the nose area is under the chin.
(Note: If the patient vomits, remove the mask and clear the patient's airway.)

Cautions ⚠
- If oxygen is used, do not smoke or use in the presence of sparking equipment or open flame.
- Re-use can result in cross-infection. Do not soak, rinse, wash, autoclave this product.

These procedures may leave harmful residues on the mask.
- This product should be used only by persons who have received adequate training.
- Dispose of the product as medical waste after use.

Shelf life
Three years from the date of manufacturing.

Contraindication
There are no noted contraindications.

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
The product should be stored on a well-ventilated indoor shelf without corrosive gases at a relative humidity of <85%. It should avoid sunlight and strong ultraviolet artificial light irradiation.

Symbol

	Manufacturer	CE	CE mark		Consult instructions for use
EC REP	Authorised Representative in the European community	UDI	Unique Device Identification		Do not reuse
	Importer	LOT	Batch code	NON STERILE	Non-sterile
MD	Medical Devices	CN	Date of manufacture, made in China	REF	Catalogue number
	Caution		Use by		Keep upright during transport
	Keep dry		Keep away from sunlight		Fragile, handle with care

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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