

Device Description and Specification

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

Resuscitation Mask

Document No.: TW/CE-04-02

Version: C/03

Basic UDI-DI: 69703857234CPR9Z

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1 Device Description and Specification

1.1 Product Name and product models

Product name of the device under evaluation: Resuscitation Mask

Product type: TW8340, TW8341, TW8342, TW8343, (with gas port and cover)

TW8340N, TW8341N, TW8342N, TW8343N (without gas port and cover)

1.2 General Description

It is made up of PVC mask (include mask, one way valve, elastic, accessory: glove). This product is mainly used to do artificial respiration on the patient, the patient before waking up in the short term to maintain normal breathing. It is an artificial ventilation of simple tools. Compared with mouth-to-mouth ventilation, which can effectively avoid the medical personnel direct contact with patients, avoid crossing infection, it can replace the mouth to mouth breathing. Don't need an electric device, convenient to carry.

It through the mouth to mask one-way valve ventilation, provide patients with auxiliary artificial respiration. easy to use and quickly. Blow air through the mouth to breathe one-way valve for the patient, patient expiration when rescue's mouth moved. Very low respiration resistance.

1.3 Intended purpose

Resuscitation Mask intended use for mouth to mask ventilation of non-breathing. It is intended to blow air (oxygen) to patients and are used to isolate emergency personnel from the victim's mouth and prevent cross infection. The mask is a non-sterile product. Single patient used.

1.4 Intended users

The product shall be used by qualified and trained medical staffs.

1.5 Basic UDI-DI

Basic UDI-DI of Resuscitation Mask:

69703857234CPR9Z

All consecutively assigned UDIs of the marketed products will be stored and can be made available upon request.

1.6 Intended Patient Population

All populations.

1.7 Certificate Number

Not applicable for Resuscitation Mask, since it is a Class I medical device.

1.8 Medical Conditions

The Resuscitation Mask is a single-use medical device, which is intended use for mouth to mask ventilation of non-breathing. It is intended to blow air (oxygen) to patients and are used to isolate emergency personnel from the victim's mouth and prevent cross infection.

There are no specific medical conditions to be diagnosed, treated or monitored.

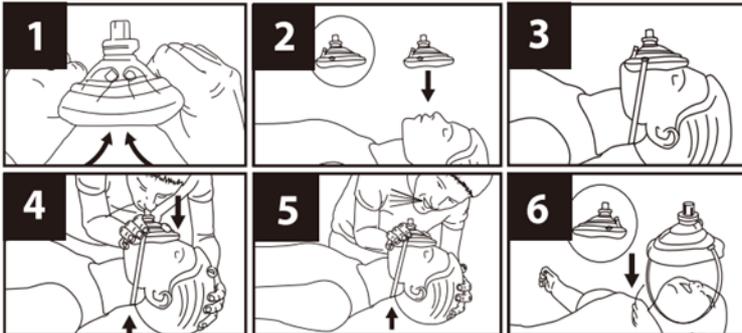
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1.9 Indications

Resuscitation Mask intended use for mouth to mask ventilation of non-breathing. It is intended to blow air (oxygen) to patients and are used to isolate emergency personnel from the victim's mouth and prevent cross infection. The mask is a non-sterile product. Single patient used.

The product has no specific indications.

1.10 Instruction for Use



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.)

1.11 Contra-indications

There are no noted contra-indications.

1.12 Complications or Side-effects

No complications or side-effects.

1.13 Warnings

- 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.
- Product should be according to the medical waste disposal after use.

1.14 Environmental protection

After using this product, the disposal of medical device waste complies with relevant regulations and environmental protection requirements.

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1.15 Principles of Operation and Mode of Action

It through the mouth to mask one-way valve ventilation, provide patients with auxiliary artificial respiration. Easy to use and quickly. Blow air through the mouth to breathe one-way valve for the patient, patient expiration when rescue's mouth moved.

1.16 Qualification as a Device according to MDR

The Resuscitation Mask is a single-use medical device intended for transient use, which is intended use for mouth to mask ventilation of non-breathing. It is intended to blow air (oxygen) to patients and are used to isolate emergency personnel from the victim's mouth and prevent cross infection. It has the function of prevention, treatment or alleviation of disease. Therefore, the product is qualified as a medical device based on definition for "medical device" in article 2 of MDR.

1.17 Risk Class

The Resuscitation Mask is non-invasive device intended for transient use, intended use for mouth to mask ventilation of non-breathing. It is intended to blow air (oxygen) to patients and are used to isolate emergency personnel from the victim's mouth and prevent cross infection. During use, the device continuous contact duration with intact skin of user shall be no more than 60 minutes. So then according to MDCG 2021-24 and Medical Device Regulation (EU) 2017/745 Annex VIII, Rule 1 ((All non-invasive devices are classified as class I), risk of class for the device is class I.

1.18 Novel Features

The Resuscitation Mask does not have novel features.

1.19 Combination with other Products

The Resuscitation Mask is intended for combination use with oxygen bag.

1.20 Configurations

N/A

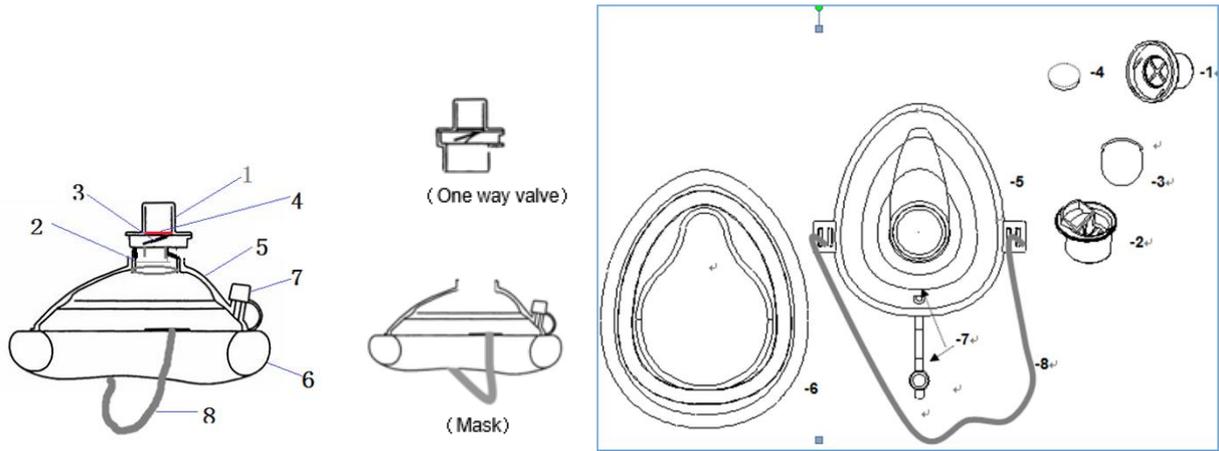
1.21 General Description of the Key Functional Elements

1.21.1 Product structure

The Resuscitation Mask is made up of PVC mask (include mask, one way valve, elastic, accessory: glove). For product picture and structure, please refer to below Figure 1 and Figure 2.

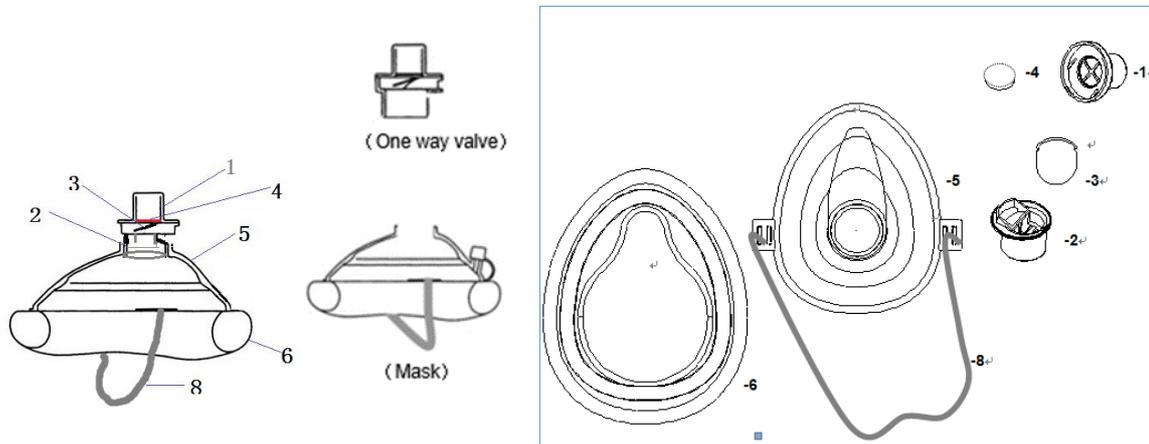


Figure 1 Product picture of Resuscitation Mask



1. Valve cover 2. Valve bracket 3. Silicone pad 4. Filter 5. Mask hoosing 6. Air cushion 7. Gas port and cover 8. Elastic

Figure 2.1 Product structure (with gas port)



1. Valve cover 2. Valve bracket 3. Silicone pad 4. Filter 5. Mask hoosing 6. Air cushion 8. Elastic

Figure 2.2 Product structure (without gas port)

1.21.2 Material key function

The product is a single use device which is intended to blow air (oxygen) to patients and are used to isolate emergency personnel from the victim's mouth and prevent cross infection. Meeting the product performance requirements depends mainly on valve cover, valve bracket, silicone pad, filter, mask hoosing, air cushion, gas port and cover and elastic.

1.21.3 Product specification and performance

1.21.3.1 Technical specification

The product is available in four types: TW8340, TW8341, TW8342 and TW8343. And the differences between four types lie in the content and packaging method. Product of types TW8340 and TW8341 are

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packed with PE bag, while TW8342 and TW8343 with PP box. The detail of specification of the Resuscitation Mask is summarized in below Table 1:

Table 1 Product specification

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

1.21.3.2 Performance Data

Performance data of the Resuscitation Mask is designed according to product technical specification requirement. Summary for the inspection/test items and result are described as below Table 2.

Table 2 The Performance Data of Resuscitation Mask

No.	Test Item	Requirement
1.	Appearance	No crackle, blemish, nick and besmirch.
2.	Cleanness	No macroscopical eyewinker and oil.
3.	Leakage	No gas leakage
4.	Expiratory resistance	< 0.5kPa (≈5cm H ₂ O) (at 50 L/min)
5.	Inspiratory resistance	< 0.5kPa (≈5cm H ₂ O) (at 50 L/min)
6.	Drop test	Drop the mask from a height of 1m onto a concrete floor in the worst case orientation.

1.22 Materials in Body Contact and Incorporated into key Functional Elements

1.22.1 List of the critical components and material in body contact, including packaging material information are summarized in below Table 3.

The provided information contains details on the raw material itself, on raw material suppliers, and product part is purchased or self-manufactured.

Table 3 List of the critical component and raw material supplier information

S/N	Part name	Material	Skin contact	
1.	One way valve	Valve cover	PVC-2310	Yes
2.		Valve bracket	PVC-2310	Yes
3.		Silicone pad	Silicone R401	No
4.		Filter	Nonwoven	No

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5.	Mask	Mask hoosing	PVC-750	No
6.		Air cushion	PVC-3055	Yes
7.		Elastic	Spandex	Yes
8.	Accessory	Glove	PVC	Yes
9.	Inner package		PP/PE	No

1.22.2 List of material in body contact, including packaging material, are summarized in below table. The provided information contains details on the raw material itself and details on body contact position and duration information.

Table 4 Detailed information of material in body contact characteristics

S/N	Part name		Material	Contact/ Not contact	Contact body part	Contact duration (single use time/ accumulation for repeat use)
1.	One way valve	Valve cover	PVC-2310	Contact	Intact skin	≤60min
2.		Valve bracket	PVC-2310	Contact	Intact skin	≤60min
3.		Silicone pad	Silicone R401	Not contact	/	/
4.		Filter	Nonwoven	Not contact	/	/
5.	Mask	Mask hoosing	PVC-750	Not contact	/	/
6.		Air cushion	PVC-3055	Contact	Intact skin	≤60min
7.		Elastic	Spandex	Contact	Intact skin	≤60min
8.	Accessory	Glove	PVC	Contact	Intact skin	≤60min
9.	Inner package		PP/PE	Not contact	/	/

1.22.3 Declaration on the Use of Substances

No medicinal substances, tissues or materials of animal origin, blood or tissues or derivatives of human origin or recombinant peptides/proteins are used on our product.

1.23 Storage and Transportation

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

1.24 Expected Shelf Life and Lifetime

The shelf life of the product is 3 years from end of manufacturing.

The lifetime of the product is 3 years from end of manufacturing.

2 Reference to Previous and Similar Generations of the Device

Original device, no previous or similar generations of the device.