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# Medical Face Mask

## 1. Indications for Use

The Medical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The Medical Face Masks are single use, disposable device, provided non-sterile.

## 2. General Description

### 2.1 Device Models

The Medical Face Masks are available with different size masks and different configurations, such as ear loop, tie on. Detailed sizes and configurations have been shown in **Table 1 Medical Face Masks Description**.

**Table 1 Medical Face Masks Description**

REF No.	Product Size	Model Description		
		Mask	Ear Loop	Tie-on
NS2R-02	17cm × 9.5cm (Adult)	X	X	
	14.5cm × 9.5cm (Children)	X	X	
NS2R-E2	17cm × 9.5cm	X		X

### 2.2 Device Design

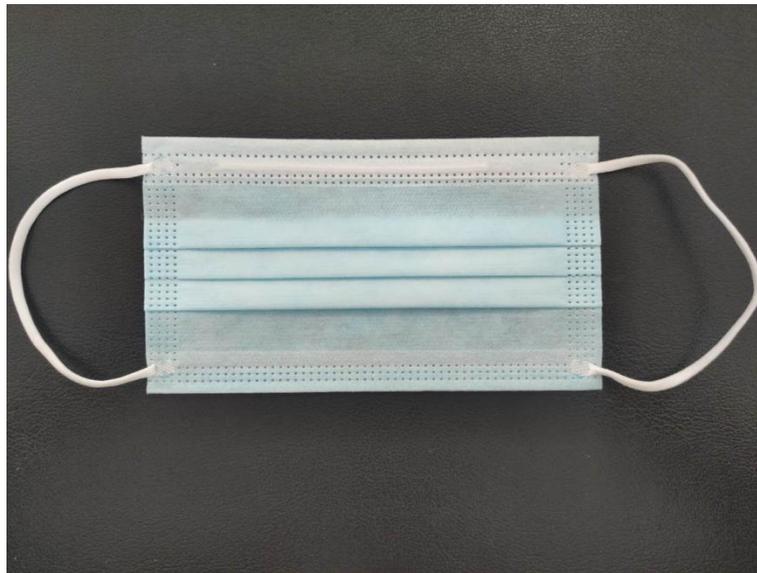
The mask is formed of three layers. The outer layer is made of blue spun-bond polypropylene non-woven, the middle layer, between the outer layer and inner layers, is made of PTFE membrane filter (polytetrafluoroethylene membrane is lined on white non-woven fabric). The inner layer (facial layer) is made of white spun-bond polypropylene non-woven. The four sides of the three layers of the mask are fused by ultrasound heat sealing machine. The pleated segments could open to a comfortable mask form covering the nose and mouth areas of the face. There is a nose piece sealed in the top side of the masks between the outer layer and middle layer. It is a malleable iron wire with white plastic covering. It is used to fix the masks on face.

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The models of the device, ear loop, is fixed to the face using the attached ear loop, the ear loop which is designed to allow easy fitting and removal is of latex free elastic. The models of the device, tie-on, is fixed to the face using the attached tie strings, the vertical tie strings are made of white spun-bond polypropylene non-woven. The elastic ear loops or tie strings are welded onto mask (the inner layer) left/right side by ultrasonic heat sealing.

### 2.3 Photograph

**Fig.1 The Medical Face Mask (Type: Ear Loop)**



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**Fig.2 The Medical Face Mask (Type: Tie-on)**

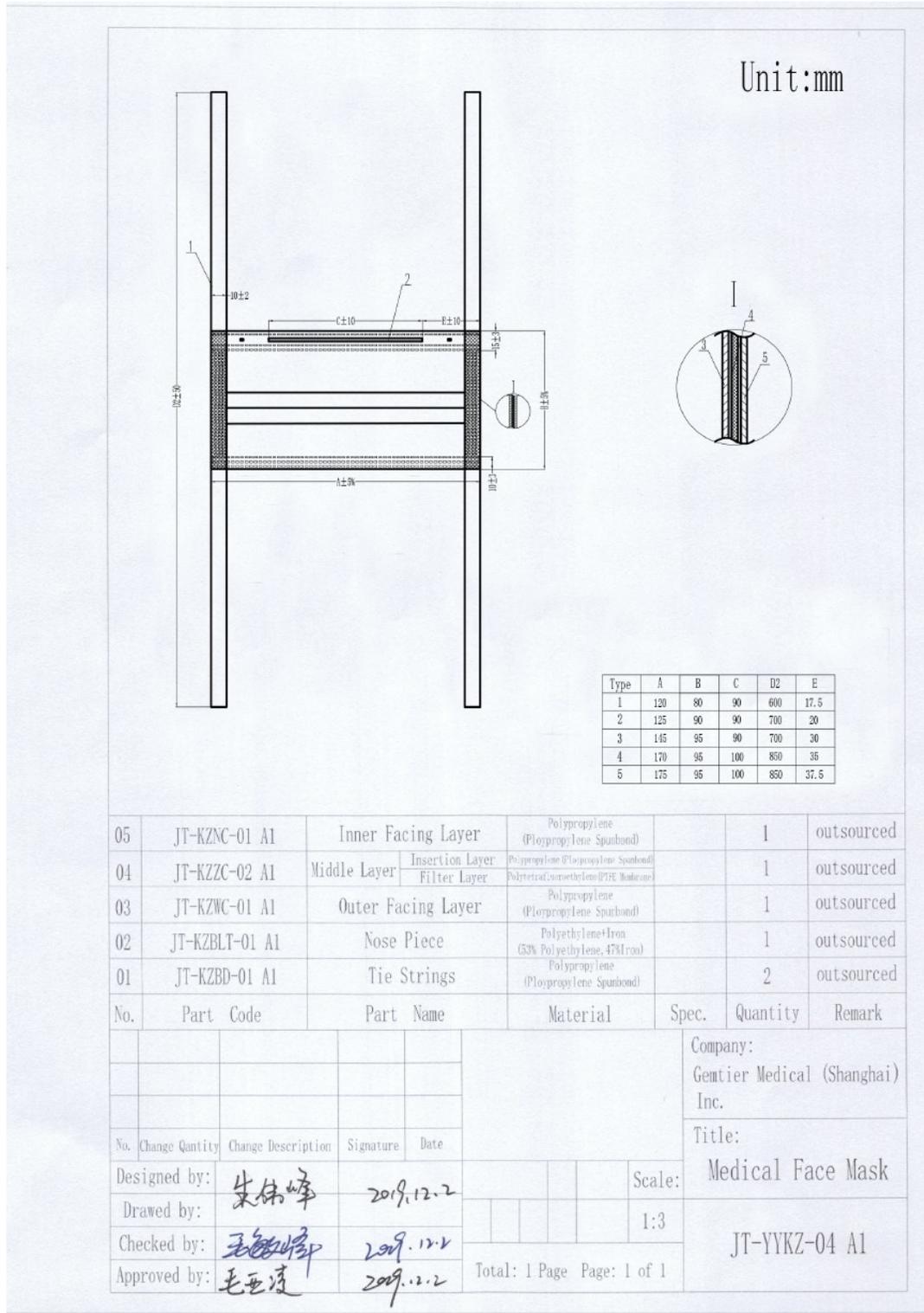


**Fig.3 Nose piece inside of the Medical Face Mask**





**Fig.5 The Medical Face Mask (Type: Tie-on)**



## 2.5 Material

### 2.5.1 Material Composition

Component			Material
Mask	Outer Layer		Spun-bond Polypropylene non-woven fabric, blue
	Middle Layer	Filter layer	Polytetrafluoroethylene (PTFE Membrane)
		Insertion Layer	PP SPUNBOND NON-WOVEN FABRIC, white
	Inner Layer		Spun-bond Polypropylene non-woven fabric, white
Noise Piece			Malleable iron wire with plastic covering
Ear Loops			Spandex elastic cord (polyurethane core with polyamide cover)
Tie Strings			Spun-bond Polypropylene non-woven fabric, white

## 2.6 Product Specification

Table 6 Specification of mask components

Type	REF No.	Product Size	Specification (unit:mm)				
			Mask		Nose Piece	Ear Loop	
			Length	Width	Length	Natural length	Tensile strength
Ear Loop	NS2R-02	17cm×9.5cm (Adult)	170	95	100	180	≥10N
		14.5cm×9.5cm (Children)	145	95	90	165	
Type	REF No.	Product Size	Specification (unit:mm)				
			Mask		Nose Piece	Tie String	
			Length	Width	Length	Length	Tensile strength
Tie-On	NS2R-E2	17cm×9.5cm	170	95	100	850	≥10N

## 2.7 Package Description

The package of each kind of mask contains paper-plastic pouch (primary package), color box and carton (transportation container).

Ten masks per paper-plastic pouch; the five pouches per color box that is made of corrugated paper, and the forty color boxes per carton that is made of corrugated paper.