

## Surgical mask medical mask with 3ply Type IIR grade

### **Product description**

Dexuan Disposable Medical/Surgical Mask with CE(EN14683)/ YY/T 0969-2013/ FDA

Standard : CE EN14683/ YY/T 0969-2013/ FDA

Bacterial Filtering rate (BFE):  $\geq 98\%$

Protection grade: IIR

Sealability : Very Good

Material: 3 Ply Meltblown Non-woven fabric, 25gsm+25gsm+25gsm

Color: light blue

Size: 17cm\*9.5cm(Length\*Width)

Type: Earloop

Package: 50pcs in one color box(19\*10\*10cm) 2000pcs/carton

### **Specification:**

3ply Class material

- 1st ply: 50/m<sup>2</sup> spun -bon PP
- 2nd ply: 25/m<sup>2</sup> melt-blown fabric
- 3rd ply: 25/m<sup>2</sup> Hot air cotton fabric

Storage temperature: -20-38°C

Storage humidity: 80%

Saline media filtration efficiency:  $\geq 99.7\%$

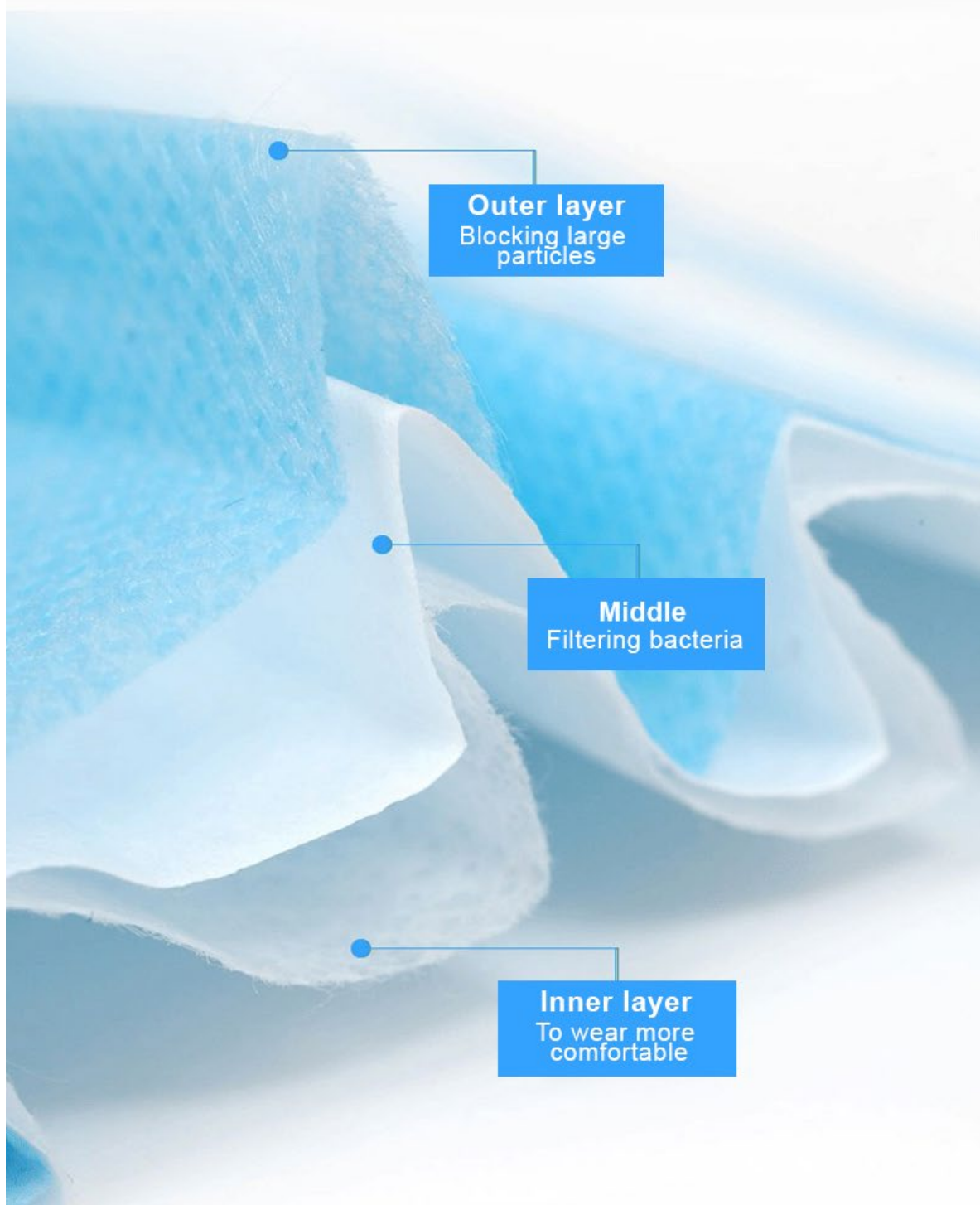
Oily media filtration efficiency:  $\geq 99.7\%$

### **Feature:**

- Multiple efficient isolation from Droplet, smog, dust, HCHO, odour, bacteria;
- Compose of new skin-friendly face fabric, efficient filter, double filter plies;
- No peculiar smell, allergy resistance and better protection your family;

# 3 PLY

DISPOSABLE MASK NON  
MEDICAL WITH EAR LOOP



# Cashmere



Breathe freely, Clean without odor



# DX-3PLY-D-2R | Disposal facial mask



**EC Declaration of Conformity**

**CE**

<b>Manufacturers Name:</b>	 HEYUAN DEXUAN MEDICAL TECHNOLOGY CO., LTD.		
<b>Manufacturers Address:</b>	No.6 of Longling 1st Road, Longling Industrial park, Yuancheng District, Heyuan, 517000, Guangdong, China		
<b>SRN (Single Registration Number):</b>	Not available yet		
<b>Authorized Representative Name (if applicable):</b>	<table border="1" data-bbox="718 705 798 750"><tr><td>EC</td><td>REP</td></tr></table> Wellkang Ltd	EC	REP
EC	REP		
<b>Authorized Representative Address (if applicable):</b>	16 Castle St, Dover, Kent, CT16 1PW, England, UK		
<b>Basic UDI-DI:</b>	CA017566		
<b>Name of the Device (s):</b>	Disposable Medical Mask (non-sterile)		
<b>Model/Specification</b>	17.5cm*9.5cm		
<b>Standards:</b>	See Annex I attached		
<b>Classification:</b>	Class I, Rule 1		
<b>Conformity assessment route:</b>	HEYUAN DEXUAN MEDICAL TECHNOLOGY CO., LTD. uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:  Class I: EC conformity declaration according to annex II + annex III		

This declaration of conformity is issued under the sole responsibility of HEYUAN DEXUAN MEDICAL TECHNOLOGY CO., LTD.. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.  
All supporting documentation is retained at the premises of the manufacturer.

<b>Signature</b> 	<b>Place and date (dd.mm.yyyy) of issue:</b>
<b>NAME</b> Liu Zhi Biao	MAY 13, 2020
<b>FUNCTION</b> CEO	Heyuan, China

# DX-3PLY-D-2R | Disposal facial mask



Ministero della Salute

## Elenco dei dispositivi medici

### Criteri di ricerca:

Denominazione fabbricante: **dexuan medical**

Codice fiscale fabbricante:

Partita IVA / VAT number fabbricante:

Codice nazione fabbricante:

Denominazione mandatario:

Codice fiscale mandatario:

Partita IVA / VAT number mandatario:

Codice nazione mandatario:

Tipologia dispositivo:

Identificativo di registrazione attribuito dal sistema BD/RDM:

Codice attribuito dal fabbricante:

Nome commerciale e modello:

Classificazione CND:

Descrizione CND:

Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

## Elenco dispositivi individuati

Dati aggiornati al:07/03/2021

DISPOSITIVO MEDICO/ASSEMBLATO							FABBRICANTE/ASSEMBLATORE						
TIPOLOGIA	IDENTIFICATIVO	ISCRITTO AL	CODICE ATTRIBUITO DAL	NOME	CLASSE	DATA PRIMA	DATA FINE	RUOLO	DENOMINAZIONE	CODICE	PARTITA	NAZIONE	
DISPOSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	COMMERCIALE	CE	PUBBLICAZIONE	IMMISSIONE	AZIENDA		FISCALE	IVA/VAT		
	BD/RDM			E MODELLO			IN	COMMERCIO			NUMBER		
Dispositivo	1977738	S	20202140721	DISPOSABLE MEDICAL MASK (NON STERILE)	T020601 - MASCHERINE CHIRURGICHE STANDARD	I - Classe I non sterile e senza funzioni di misura	17/07/2020	FABBRICANTE	HEYUAN DEXUAN MEDICAL TECHNOLOGY CO., LTD.			CN	
								MANDATARIO	WELLKANG LTD		GB4740528	GB	