



Microgen

**BARBIJO  
QUIRURGICO**

**TRICAPA ANTIBACTERIAL  
PROTECCION FFP2**



**C**  **VID-19**



CALL CENTER  
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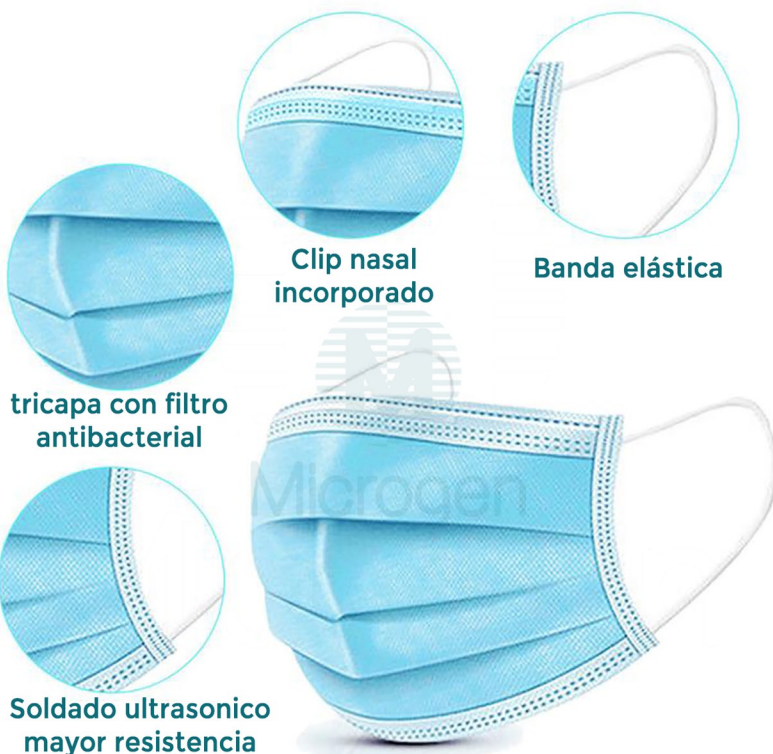
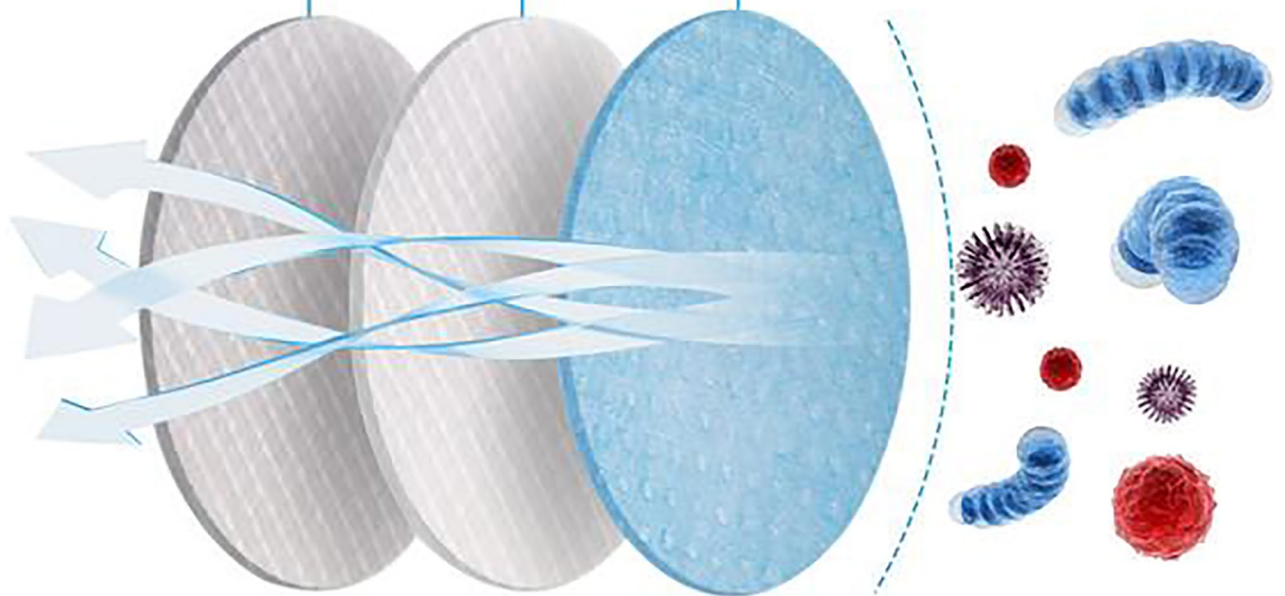
# BARBIJO DESCARTABLE TRICAPA NIVEL FFP2

Filtra el 96% de partículas aéreas,  
humos, polvo, polen, etc



Testeado FFP2  
Aprobado FDA EEUU

- **Capa filtrante**  
filtro meltblown  
alta eficiencia
- **Capa interna**  
suave y respirable
- **Capa exterior**  
tela no tejida 25gs  
bloquea el polvo



Respiración libre, baja resistencia a la exhalación  
Filtración de alta eficiencia  
La superficie está cubierta de poros lo que permite  
experimentar una alta ventilación y una respiración suave



# INFORMACION ADICIONAL CERTIFICACIONES TESTS



Fiscal Year 2020

## CERTIFICATION OF FDA REGISTRATION

This certifies that:

**CHANGZHOU DENG FENG ELECTRICAL CO., LTD**

**No. 128 East Rd Guangdian, Hutang Town Wujin Dist.**

**Changzhou, Jiangsu 213161, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

**Shenzhen CCT Testing Technology Co., Ltd.**

**Owner/Operator Number: 10065110**



Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D380669	KHA	MASK, SCAVENGING	Disposable Protective MASK

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CCT is not affiliated with the U.S. Food and Drug Administration.



# 检验检测结果

## Testing Results

STFWT20203319

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序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	外观要求	—	口罩表面不应有破损、油污斑渍、变形及其他明显的缺陷。	口罩表面无破损、油污斑渍、变形及其他明显的缺陷。	合格
2	口罩下方视野	—	≥60°	66°	合格
3	口罩带及口罩带与口罩体的连接处断裂强力	N	≥10	1#: 试样断裂强力不小于 10N 2#: 试样断裂强力不小于 10N 3#: 试样断裂强力不小于 10N	合格
4	pH 值	—	4.0-7.5	6.3	合格
5	甲醛含量	mg/kg	≤20	未检出	合格
6	细菌过滤效率/% (BFE)	—	≥95	96.2	合格
7	通气阻力	Pa	≤80	4#: 79 5#: 78 6#: 70	合格
8	颗粒过滤效率/% (PFE)	—	≥80	1#: 87.7 2#: 87.3 3#: 86.9	合格
备注	甲醛含量小于 20 mg/kg, 试验结果报告“未检出”				

**\* BFE (EFICIENCIA DE FILTRACION BACTERIANA) MAYOR AL 96%**

**- LA BFE MIDE LA CAPACIDAD DE LA MASCARILLA PARA CAPTURAR GOTÍCULAS POTENCIALMENTE PORTADORAS DE BACTERIAS QUE EMITE EL USUARIO DE ESTA.**

**LA RESPIRABILIDAD ES UN INDICADOR DE COMODIDAD DE USO.**

**- LAS DE TIPO I DEBEN EMPLEARSE SOLO PARA PACIENTES Y OTROS USUARIOS CON EL OBJETIVO DE REDUCIR EL RIESGO DE QUE PUEDAN TRANSMITIR INFECCIONES, PARTICULARMENTE EN SITUACIONES DE EPIDEMIAS O PANDEMIAS.**