

# CATÁLOGO DE PRODUCTOS **PROTECCIÓN MÉDICA**

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COGAR  
HMDC



# MASCARILLA DE PROTECCIÓN RESPIRATORIA

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## **TIPO NORMAL**



**Fuerte** barrera  
**Respira** libremente  
**Clip** ajustable  
**Filtrado** de 3 capas

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Modelo: **KZ01**  
**Tela de 3 capas** - No tejidas

# MASCARILLA DE PROTECCIÓN RESPIRATORIA

## TIPO NORMAL

序号	检测项目	检测方法	单位	标准要求 (D级)	实测值	单项评价	结果备注
1	呼吸阻力	GB/T 32610-2016	Pa	≤175	51.6	符合	—
	呼气阻力		Pa	≤145	61.0		
2	过滤效率	GB/T 32610-2016 附录 A	%	≥90	90.9	符合	—
3	防护效果	GB/T 32610-2016 附录 B	%	≥65	65.1	符合	—
4	标识	GB/T 32610-2016 8.2	制造商名称和地址	符合 GB/T32610-2016 标准要求	符合标准	符合	—
	产品名称		符合 GB/T32610-2016 标准要求	符合标准			
	主要原材料		符合 GB/T32610-2016 标准要求	符合标准			
	执行标准编号		符合 GB/T32610-2016 标准要求	符合标准			
	产品防护效果级别		符合 GB/T32610-2016 标准要求	符合标准			
	产品规格		符合 GB/T32610-2016 标准要求	符合标准			
	使用说明		符合 GB/T32610-2016 标准要求	符合标准			
	生产日期、推荐使用时间		符合 GB/T32610-2016 标准要求	符合标准			

## CERTIFICADO DE GARANTÍA

# MASCARILLA DE PROTECCIÓN RESPIRATORIA

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## **KN95 - FFP3**



Verificación standar  
Eficiencia de filtración **BFE 95%**  
No alérgico  
No produce irritación

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**CE 149:2001 + A1:2001**



# MASCARILLA DE PROTECCIÓN RESPIRATORIA

## KN95 - FFP3

Form QAT\_10-MD4, version 00, effective since March 6th, 2020

### Certificate of Compliance



No. OP20031 S.FRLUT25  
Technical Construction File no. TPGD20031022120

**Certificate's Holder:**

**Certification ECM Mark:**



**Product:** Kn95 mask  
**Model(s):** Class of device: FFP3

**Verification to:** Standard: EN 149:2001+A1:2009  
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

**Remarks:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

**Additional information and qualification about the Marking:**

**CE** The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RGD1\_ECM rev.3 available at: [www.enfotecma.it](http://www.enfotecma.it)

**Issuance date:** 15 March 2020  
**Expiry date:** 14 March 2025

**Reviewer:** Technical expert Amanda Payne  
**Approver:** ECM Service Director Luca Bedonni




### CE Technical Documentation Review Report

**Applicant:**

**Report Number:** 16805229.001

**Examination intent:** Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

**Product(s):** Non-sterile medical non-woven products

Caps	UMDNS Code 13-882
Coveralls	UMDNS Code 20-346
Face masks	UMDNS Code 12-458
Surgical gowns	UMDNS Code 11-901

**Type(s)/Model(s):** -----

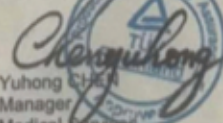
**Classification:** Class I (according to manufacturer's declaration)

**Examination period:** Dec.11.2015

**Date of expiry:** Dec.10.2020

**Review result:** During the examination of the provided Technical Documentation (No: DC-2015CE01, DC-2015CE02, DC-2015CE03, Revision 01, Dated Jul.18.2015), no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

TÜV Rheinland (China) Ltd.



Yuhong  
Manager  
Medical Services

## CERTIFICADO DE GARANTÍA

# EQUIPO AISLAMIENTO MÉDICO DESECHABLE

## EPI - Equipo protección individual



**Transpirable, a prueba de polvo y a prueba de líquidos**, uso de tela no tejida como materia prima principal, **hecha por corte, costura, cuerpo de triplete**. Aislamiento general en instituciones médicas, clínicas ambulatorias, salas de inspección, etc.

**Protección de los trabajadores de la salud contra la contaminación con sangre, fluidos corporales y otros agentes infecciosos, o protección contra la infección de los pacientes.**



# EQUIPO AISLAMIENTO MÉDICO DESECHABLE

## **EPI - Equipo protección individual**

### CERTIFICATE OF COMPLIANCE

Certificate Number UCN : 2020031202PPE  
Date of Issue : 2020-03-12  
Product description : Disposable medical isolation gown  
Model N : L, XL, XXL  
Test Report : SCC(20)-311-3-11

Test required :  
*EN 14126:2003*

Conclusion :  
The product meets the technical requirement of the above standards and hence fulfils the technical requirements of the following directives  
*(EU)2016/425 Personal protective equipment (PPE)*

*This certificate is only valid for the equipment and configuration described, in conjunction with the test data details above .*

The CE mark as show below can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of Conformity and compliance with all relevant EC Directives.



*Copyright of this Certificate is owned by DEMK international and may not be reproduced other than in full and with the prior approval of the General Manager.*

The producer is authorized to put on the instruction manual, in the box and/or in the product the following text:

If you want to check the authenticity of this certificate go in the E-mail site

## CERTIFICADO DE GARANTÍA

## OTROS COMPLEMENTOS

# Productos médicos homologados

PRODUCTO	FÓRMULA DE PAGO: 50% ADELANTADO RESTO ANTES DE ENVÍO
 <b>NORMAL</b>	PEDIDO MINIMO 100.000 UNIDADES. CAPACIDAD MAXIMA SEMANA 5.000.000 U
 <b>FFP2</b>	PEDIDO MINIMO 10.000 UNIDADES. CAPACIDAD MAXIMA SEMANA 1.000.000 U
 <b>KN95/FFP3</b>	PEDIDO MINIMO 10.000 UNIDADES. CAPACIDAD MAXIMA SEMANA 2.000.000 U
 <b>TRAJE</b>	PEDIDO MINIMO 5.000 UNIDADES. CAPACIDAD MAXIMA SEMANA 1.000.000 U
 <b>GAFAS</b>	PEDIDO MINIMO 5.000 UNIDADES. CAPACIDAD MAXIMA SEMANA 100.000 U
 <b>PROTECTOR CARA</b>	PEDIDO MINIMO 5.000 PIEZAS

GUANTES CAJA 100 UNIDADES - TALLAS P S M L XL		
 <b>LATEX 1</b>		PEDIDO MINIMO 5.000 CAJAS. CAPACIDAD MAXIMA SEMANA 70.000 CAJAS
 <b>LATEX 2</b>		PEDIDO MINIMO 5.000 CAJAS. CAPACIDAD MAXIMA SEMANA 70.000 CAJAS
 <b>NITRILO</b>		PEDIDO MINIMO 5.000 CAJAS. CAPACIDAD MAXIMA SEMANA 7.000 CAJAS
 <b>PVC</b>		PEDIDO MINIMO 5.000 CAJAS. CAPACIDAD MAXIMA SEMANA 70.000 CAJAS

Sólo trabajamos con **productos de la máxima calidad y eficacia.**