



Ficha Técnica de Producto

Ref. 3500N

Mascarilla Quirúrgica Tipo IIR Con Gomas

Luhepa

INTERNACIONAL, S.L.

Member of
Uhealth Medical Group

Información Técnica:

Modelo Fabricante : LHKL-BA-1

Mascarilla Quirúrgica Tipo IIR , fabricada en tres capas de tela no tejida y tejido filtrante, con tira nasal moldeable en Acero+PP y dos gomas de ajuste suaves.

1ª CAPA	2ª CAPA	3ª CAPA
Tela No Tejida 25g	Melt-Blown 25g	Tela No Tejida 20g

Clip Nariz: 11 cm

Elásticos de Ajuste: 17,5 cm

Medidas Mascarilla: 17,5 x 9,5 cm

Color: NEGRO

Mascarilla y Gomas libres de Látex, Grafeno y Fibra de Vidrio, no produce irritaciones.

Normativas y Uso:

Producto Conforme al **Reglamento UE 2017/745** relativo a los productos sanitarios - Clase I

Producto Fabricado bajo los estándares de la Norma **ISO 13485:2003+AC2007**.

La Mascarilla responde ante las exigencias de la norma **EN 14683:2019+AC2019**

Ensayo N°: GPL3J3KO235225L1

Laboratorio Acreditado por CNAS N°: L0412

Ensayo N°: GPL3J3KO235235L1

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Eficiencia de Filtración Bacteriana	Respirabilidad/Presión Diferencial	Limpieza Microbiana/Carga Biológica	Presión de Resistencia a Salpicaduras
>= 98%	< 60%	<= 30 UF/g	>=16

Instrucciones de Uso:

Comprobar el estado de la mascarilla y caducidad antes de su uso.

No utilizar la mascarilla por un tiempo superior a 4 horas

Lávese las manos antes de utilizar la mascarilla y toque únicamente la goma de la mascarilla

Colocar la mascarilla sobre nariz/boca y pasar las gomas por detrás de las orejas.

Ajustar adecuadamente la tira nasal y zona del mentón.

Evitar en todo momento tocar o manipular la mascarilla durante su uso.

Información Logística:

Etiquetado Conforme a la Norma 14683:2019+AC:2019 y Producto Sanitario Clase I.

Presentación:

- Estuche Dispensador de 50 unidades
- Embalaje Master de 2.000 unidades (40 dispensadores)
- Euro Palets de 25 Cajas

Cod EAN: 9 6974100420430 - Made in China

UDI-DI Básico: 6974100423500NTW

Almacenar en un lugar seco, limpio y a temperaturas oscilantes entre 5° y 35°. No exponer de manera directa a la luz solar



DECLARACIÓN DE CONFORMIDAD



Reglamento (UE)2017/745 Sobre Productos Sanitarios

Fabricante: Uhealth Medical (Beijing) Protective Products Co., Ltd.

Dirección: Room 703, No. 19 Bulding, No 16, Ma Zhu Road
Zhang Ziyin Town, Daixing District, Beijing, China

SRN: CN-MF-000010566

Representante CE: MedPath GmbH.

Dirección: Mies-van-der-Rohe-Strasse 8 - 80807 Munich, Germany

SRN Rep UE: DE-AR-000000087

Información Sobre Producto

Descripción: Mascarilla Quirúrgica Tipo IIR Con Gomas

Marca: Uhealth

Color: Negro

Modelo: LHKL-BA-1

Packing: Embalaje de 2.000 unidades (40x50)

Basic UDI-DI: 6974100423500NTW

Clasificación: Clase I

Norma: EN 14683:2019 + AC:2019

Procedimiento Evaluación de la Norma: Anexo II+III del Reglamento (EU) 2017/745

Por la Presente declaramos que los productos mencionados anteriormente cumplen los requisitos del Reglamento sobre Productos Sanitarios (UE) 2017/745 y la siguientes normas armonizadas

EN ISO 14971: 2012

EN ISO 15223-1:2016

EN ISO 1041:2008+A1:2013

En Beijing/ China a 01 de Enero de 2024

For and on behalf of
Uhealth Medical (Beijing) Protective Products Co., Ltd.
北京联合康力医疗防护用品有限公司


.....
Authorized Signature(s)

Cybil Zhai // General Manager Uhealth Medical



Uhealth Medical (Beijing) Protective Products Co., Ltd.

1st Floor, Building 2, No. 15, Jingsheng South Fourth Street, Tongzhou District, Beijing, P.R. China
T. 0086-87927887 Email: sales@uhealthbj.com Web: www.uhealthbj.com

Declaración Técnica

Fecha: 01 de Enero de 2024

Nosotros, Uhealth Medical (Beijing) Protective Products Co., Ltd. declaramos bajo nuestra responsabilidad que la mascarilla comercializada por la comercial Luhepa Internacional, S.L. (B01985480), corresponde a nuestro modelo y especificaciones que siguen:

Modelo Ref. LHKL-BA-1 = Ref. 3500N

- **Medidas:** 17,5 x 9,5 cm +/-0,5cm
- **Composición Capas:** (Materias Primas Usadas) 20+25+25g
- **Clip Nasal:** 11cm
- **Gomas:** 17,5 cm
- **Color:** Negro
- **BFE:** =>99%

Certificates:

Declaración de conformidad CE, acorde al reglamento (EU) 2017/745

Test Report:

EN14683 Type IIR - Adjunto

Representante Europeo

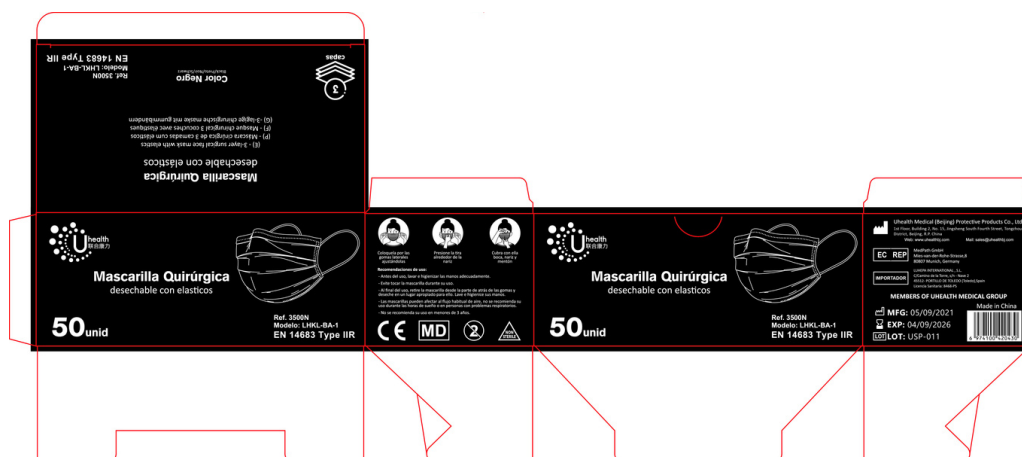
MedPath GmbH

Mies-van-der-Rohe-Strasse8

80807 Munich, Germany

CE Registrarion Number: DE/CA61/1M50/139

Declaramos que el producto no contiene entre sus materias primas, ni ha sido usado en su proceso de fabricación, envasado y manipulación **Grafeno, Látex y Fibra de Vidrio.**



Fecha: 01 de Enero de 2024

General Manager: Cybil Zhai

For and on behalf of
Uhealth Medical (Beijing) Protective Products Co., Ltd.
北京联合康力医疗防护用品有限公司
Cybil Zhai
Authorized Signature(s)

Sello y Firma Legal de la Empresa y
Representante.



Información de Producto

Ref. 3500N

Mascarilla Quirúrgica Tipo IIR Con Gomas

Luhepa

INTERNACIONAL, S.L.

Member of
Uhealth Medical Group

Información Gráfica:

Embalaje Master



Foto Producto



Embalaje Dispensador:



Información Logística:

Estuche Dispensador de 50 unidades



50 unid

Embalaje Master de 2.000 unidades (40 dispensadores)

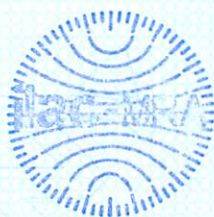


2.000 unid

Euro Palets de 25 Cajas



25 Cajas



中国认可
国际互认
检测
TESTING
CNAS L0412

检测报告

(Test Report)

No. GPL3J3KO235235L1

样品名称
(Sample Description)

一次性医用口罩
Medical Disposable Face mask

委托单位
(Applicant)

北京联合康力医疗防护用品有限公司
Uhealth Medical (Beijing) Protective Products
Co.,Ltd.



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检测结果

(Test Results)

No. GPL3J3KO235235L1

第 1 页, 共 2 页 (page 1 of 2)

样品名称 (Sample Description)	一次性医用口罩 Medical Disposable Face mask	样品规格 (Sample Specification)	17.5×9.5cm
委托单位 (Applicant)	北京联合康力医疗防护用品 有限公司 Uhealth Medical (Beijing) Protective Products Co.,Ltd.	商标 (Trade Mark)	—
到样日期 (Received Date)	2021-09-26	生产日期或批号 (Manufacturing Date or Lot No.)	2021/9/5 /USP-011
检测日期 (Test Date)	2021-09-26~2021-10-08	样品等级 (Sample Grade)	—
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩细菌过滤效率检测仪 等 Mask bacteria filtration efficiency detector etc.		
备注 (Note)	1.型号: LHKL-BA-1 Model: LHKL-BA-1 2.生产单位/受检单位: 北京联合康力医疗防护用品有限公司 Manufacturer/ Tested company: Uhealth Medical (Beijing) Protective Products Co.,Ltd. 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant. 5.限值标准: EN 14683:2019+AC:2019(E) (IIR 型) Limit Standard: EN 14683:2019+AC:2019(E) (Type IIR)		
	编制人 (Edited by)	唐興	
	审核人 (Checked by)	杜春林	
	批准人 (Approved by)	杜春林	
	签发日期 (Issued Date)	2021 年 10 月 08 日	

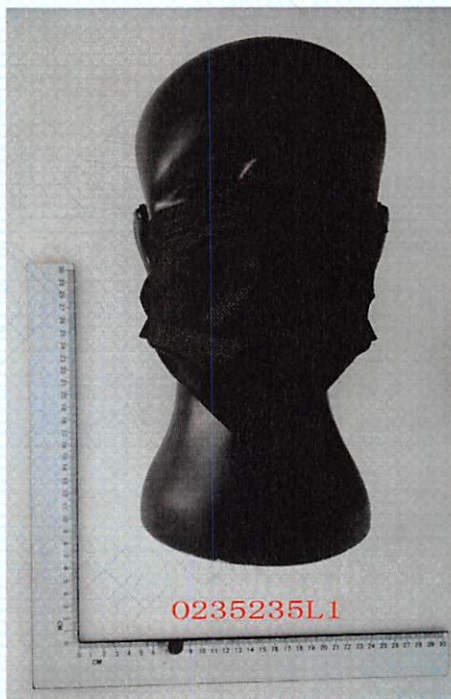
检测结果 (Test Results)

No. GPL3J3KO235235L1

第 2 页, 共 2 页 (page 2 of 2)

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)	单项结论 (Evaluation)	检测方法 (Test Method)
1	细菌过滤效率 (BFE) Bacterial filtration efficiency(BFE)	%	≥ 98	> 99.99	符合 Pass	EN14683: 2019+AC: 2019(E) 附录 B Appendix B
				99.95		
				> 99.99		
				99.95		
				99.89		
2	微生物洁净度 Microbial cleanliness	cfu/g	≤ 30	12	符合 Pass	EN14683: 2019+AC: 2019(E) 附录 D Appendix D
				10		
				6		
				9		
				9		

照片 Photo:



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中国认可
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检测
TESTING
CNAS L0412

检测报告 (Test Report)

No. GPL3J3KO235225L1

样品名称
(Sample Description)

一次性医用口罩
Medical Disposable Face mask

委托单位
(Applicant)

北京联合康力医疗防护用品有限公司
Uhealth Medical (Beijing) Protective Products
Co.,Ltd.



查询密码:rdz2sf9

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(0512)62997900

检测结果

(Test Results)

No. GPL3J3KO235225L1

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样品名称 (Sample Description)	一次性医用口罩 Medical Disposable Face mask	样品规格 (Sample Specification)	17.5×9.5cm
委托单位 (Applicant)	北京联合康力医疗防护用品 有限公司 Uhealth Medical (Beijing) Protective Products Co.,Ltd.	商标 (Trade Mark)	—
到样日期 (Received Date)	2021-09-26	生产日期或批号 (Manufacturing Date or Lot No.)	2021/9/5 /USP-011
检测日期 (Test Date)	2021-09-26~2021-10-01	样品等级 (Sample Grade)	—
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩细菌过滤效率检测仪 等 Mask bacteria filtration efficiency detector etc.		
备注 (Note)	1.型号: LHKL-BA-1 Model: LHKL-BA-1 2.生产单位/受检单位: 北京联合康力医疗防护用品有限公司 Manufacturer/ Tested company: Uhealth Medical (Beijing) Protective Products Co.,Ltd. 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant. 5.限值标准: EN 14683:2019+AC:2019(E) (IIR 型) Limit Standard: EN 14683:2019+AC:2019(E) (Type IIR)		
	编制人 (Edited by)	唐兴	
	审核人 (Checked by)	杜永华	
	批准人 (Approved by)	杜永华	
	签发日期 (Issued Date)	2021 年 10 月 01 日	

检测结果 (Test Results)

No. GPL3J3KO235225L1

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序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)			单项结论 (Evaluation)	检测方法 (Test Method)
1	压力差 Differential pressure	Pa/cm ²	<60	A	B	C	符合 Pass	EN 14683:2019+ AC:2019(E) 附录 C Appendix C
				1-1	55.7	50.1		
				1-2	41.4			
				1-3	55.7			
				1-4	50.4			
				1-5	47.1			
				2-1	45.7	47.9		
				2-2	47.3			
				2-3	42.0			
				2-4	54.1			
				2-5	50.6			
				3-1	56.5	51.6		
				3-2	55.1			
				3-3	49.4			
				3-4	48.8			
				3-5	48.0			
				4-1	58.0	51.2		
				4-2	58.8			
				4-3	46.9			
				4-4	45.9			
				4-5	46.3			
				5-1	58.2	52.7		
				5-2	46.1			
				5-3	57.8			
				5-4	50.0			
				5-5	51.6			
2	抗溅压力 Splash resistance pressure	kPa	≥16.0	32 个试样均>16.0 Splash resistance pressure of 32 samples were all greater than 16.0			符合 Pass	ISO 22609:2004 EN 14683:2019+ AC:2019
备注 Note: A-试样编号-测试区域编号 Test Specimen number-Test area number: B-每个测试区域的压力差 Differential pressure for each test area: C-每个试样的平均压差 The averaged differential pressure for each test specimen.								

备注 Note: A-试样编号-测试区域编号 Test Specimen number-Test area number; B-每个测试区域的压力差 Differential pressure for each test area; C-每个试样的平均压差 The averaged differential pressure for each test specimen.

检测结果 (Test Results)

No. GPL3J3KO235225L1

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照片 Photo:



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