Luhepa
INTERNACIONAL, S.L.
Member of
Uhealth Medical Group

FICHA TÉCNICA
de producto

Ref. 3500N
Mascarilla Quirúrgica Con Gomas IIR

Mascarilla Quirúrgica Premium de máxima protección y filtración Tipo IIR , fabricada en tres capas de tela no tejida y tejido filtrante, con tira nasal moldeable en acero plastificado y dos gomas de ajuste suaves.

Características

- **Modelo Fabricante: LHKL-BA-1**
- Materia Prima:
  - 1ª Capa - Tela No Tejida 25grs
  - 2ª Capa - MeltBlown 25grs
  - 3ª Capa - Tela No Tejida 22 grs
- Clip Nasal: 11 cm
- Elásticos de Ajuste 17,5 cm
- Repelente a salpicaduras
- UN SOLO USO
- Producto Hipoalergénico
- Producto Libre de Látex, Grafeno, Ftalatos y Fibra de Vidrio, no produce irritaciones.

Colores Disponibles

Normativas

- Producto Conforme Reglamento **UE 2017/745**, relativo a los productos Sanitarios - **Clase I**
- Producto Conforme al **Real Decreto 1591/2009** referido a la regulación de productos sanitarios
- Producto Fabricado bajo los estándares de la Norma **ISO 13485:2016.**
- Producto Fabricado bajo las exigencias de la Norma **EN 14683:2019+AC2019**
- Ensayo Nº: GPL3J3KO235235L1 - Laboratorio acreditado por CNAS con Nº: L0412
- Ensayo Nº: GPL3J3KO235225L1 - Laboratorio acreditado por CNAS con Nº: L0412
  - Eficiencia de Filtración Bacteriana >= 98%
  - Respirabilidad/Presión Diferencial <60%
  - Limpieza Microbiana/Caga Biológica <=30 UF/g
  - Presión de Resistencia a Salpicaduras >=16

Instrucciones de uso

- Comprobar antes del uso es estado del embalaje y la fecha de caducidad del mismo.
- Lávese las manos antes de de utilizar el producto y asegúrese de tocas únicamente la goma de las mascarilla
- Colocar la Mascarilla sobre la 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, que no debe exceder de un tiempo máximo de 4 horas

Almacenaje

- Almacenar en un lugar seco, limpio y a temperaturas oscilantes entre 5ºC y 35ºC.
- No exponer de manera directa a la luz solar
- Caducidad - 5 años desde la fecha de Fabricación

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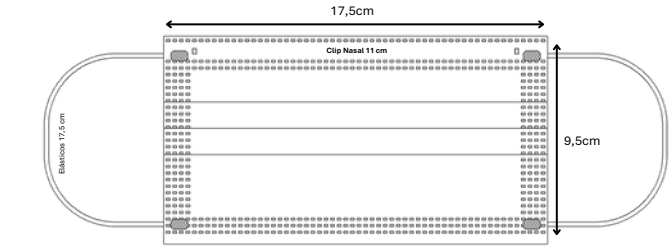
de producto

Ref. 3500N

Especificaciones Técnicas y Fotos Técnicas del Embalaje



Información Logística

- Etiquetado conforme a las diferentes normas de aplicación en términos de descripciones y pictogramas.
- Presentación:
  - Estuche Dispensador de 50 unidades
  - 40 Dispensadores por embalaje
  - Embalaje master (Caja) con un total de 2.000 unidades
  - Indicaciones de Referencia, Descripción de Producto, Lote, Fabricación y Caducidad en embalaje interior y caja exterior.
  - Medidas de la Caja: 49,5x39x33,5
  - Peso de la Caja: 8,00 Kg
  - Euro Palets de 25 Cajas
    - 5 Filas por Palet - 5 Cajas por Fila.
- Códigos informativos de los embalajes:

Referencia	Color	EAN-13 Dispensador	GTIN-14 Caja Exterior
3500N	Negro	6 974100 42043 0	(01)169 741004 2043 7

Luhepa Internacional, S.L.

Camino de la Torre, Nave 2 - CP: 45512 Portillo de Toledo (Toledo) - España
CIF: B-01985480 // Licencia Sanitaria Importador AEMPS: 8468-PS // Registro Sanitario Alimentario: 39.006740/TO
SRN Representante UE Productos Sanitarios: ES-AR-000043668 // SRN Importador Productos Sanitarios UE: ES-IM-000042791
Tlf: +34 925 678 656 - Mail: luhepa@luhepa.es - www.luhepa.es

Uhealth Medical (Beijing) Products Co., LTD

ROOM 703, No.19 Building, No.16, MA ZHU ROAD, ZHANG ZIYING TOWN,
DAXING DISTRICT, BEIJING, CHINA
T. 0086-87927887 Email: sales@uhealthbj.com Web: www.uhealthbj.com

Declaración UE de Conformidad

Reglamento (UE)2017/745 Sobre Productos Sanitarios

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

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

SRN Fabricante: CN-MF-000010566

Representante Legal Autorizado en la Unión Europea: MedPath GmmH.

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

SRN Representante UE: DE-AR-00000087

Importador para la Unión Europea: Luhepa Internacional, S.L.

Dirección: Camino de la Torre, Nave 2 - CP: 45512 - Portillo de Toledo (Toledo)

SRN Importador: ES-IM-000042791

Información Sobre Producto

Descripción: Mascarilla Quirúrgica Tipo IIR con Gomas - Ref. 3500N

Color: Negro

Modelo: LHKL-BA-1

Packing: Embalaje de 2.000 unidades (40 dispensadores de 50 unidadees)

Basic UDI-DI: 6974100423500AT4

Finalidad Prevista: Protección Respiratoria para uso de aislamiento general en pacientes, visitantes o personal sanitario en centros de salud, laboratorios y hospitales.

Clasificación de Riesgo: Clase I según el Artículo 1 del anexo VIII del Reglamento sobre Productos Sanitarios UE 2017/745 del 5 de abril de 2017.

Procedimiento de Evaluación de la Conformidad: Anexo II y III del Reglamento US 2017/745 del 5 de abril de 2017

Por la presente declaramos bajo nuestra exclusiva responsabilidad que los productos mencionados anteriormente cumplen los requisitos del Reglamento sobre productos Sanitarios (UE) 2017/745 y las siguientes normas armonizadas:

EN ISO 14971:2012

EN ISO 15223-1:2016

EN ISO 1041:2008+A1:2013

Esta Declaración esta respaldada por la aprobación del Sistema de Calidad ISO 13485:2016 emitido por BCC Int - (miembro de IAF y UKAS Management System 8631) con Número de Registro UKZB23MD30059R0S

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

En Beijing/China a 01 de Enero de 2025

Uhealth Medical (Beijing) Products Co., LTD

ROOM 703, No.19 Building, No.16, MA ZHU ROAD, ZHANG ZIYING TOWN,
DAXING DISTRICT, BEIJING, CHINA
T. 0086-87927887 Email: sales@uhealthbj.com Web: www.uhealthbj.com

Información Técnica

Nosotros, Uhealth Medical (Beijing) Products, Co., LTD. declaramos bajo nuestra absoluta responsabilidad que nuestra mascarilla quirúrgica comercializada Luhepa Internacional, S.L. (B01985480), corresponde a nuestro modelo y especificaciones que sigue:

Modelo Ref. LHKL-BA-1

- **Medidas:** 17,5 x 9,5 cm +/-0,5cm
- **Composición Capas:** (Materias Primas Usadas) 25+25+22g
- **Clip Nasal:** 11cm
- **Gomas:** 17,5 cm
- **Color:** Negro
- **BFE:** =>99%

Certificates:
Declaración de conformidad CE, acorde al reglamenteo (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, Ftalatos y Fibra de Vidrio.**

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

En Beijing/China a 01 de Enero de 2025

PONY 谱尼测试
Pony Testing International Group

集团微信订阅号 集团微信服务号

CMA
160000343608

CNAS
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.

PONY 谱尼测试
Pony Testing International Group

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If the applicant has any questions about the results, shall provide a written retest application with the original report, and prepay the retest fees to PONY within fifteen days since the approval date (as an exception, it shall be within five days since the date received for the primary agriculture products report).

4. 委托单位办理完毕以上手续后，本单位会尽快安排复测。如果复测结果与异议内容相符，本单位将退还委托单位的复测费。
After the applicant finishes the procedure mentioned above, PONY shall arrange the retest as soon as possible. If the retest result accords with the applicant dissent, PONY shall refund the retest fees.

5. 不可重复性或不能进行复测的实验，不进行复测，委托单位放弃异议权利。
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6. 委托单位对样品的代表性和资料的真实性负责，否则本单位不承担任何相关责任。
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WWW.PONYTEST.COM

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北京谱尼科技公司:(010)80415661
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内蒙古医学实验室:(0471)3450025
呼和浩特实验室:(0471)3450025
郑州实验室:(0371)69350670
郑州协力润华医学实验室:(0371)63279066
苏州汽车安全带及儿童安全座椅谱尼实验室:(0512)62997900

检 测 结 果
(Test Results)

No. GPL3J3KO235235L1

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)		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)		
	审核人 (Checked by)		
	批准人 (Approved by)		
	签发日期 (Issued Date)	2021 年 10 月 08 日	

谱尼测试集团股份有限公司
公司地址：北京市海淀区锦带路 66 号院 1 号楼 5 层 101
检测地址：北京市海淀区锦带路 66 号院 1 号楼
电话：010-83055000 传真：010-82619629

检测结果
(Test Results)

No. GPL3J3KO235235L1

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：

————以下空白————
(End of Report)

谱尼测试集团股份有限公司
公司地址：北京市海淀区锦带路 66 号院 1 号楼 5 层 101
检测地址：北京市海淀区锦带路 66 号院 1 号楼
电话：010-83055000 传真：010-82619629

CMA 160000343608

CNAS 中国认可 国际互认 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.

PONY 谱尼测试
Pony Testing International Group

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5. 不可重复性或不能进行复测的实验，不进行复测，委托单位放弃异议权利。
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6. 委托单位对样品的代表性和资料的真实性负责，否则本单位不承担任何相关责任。
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检 测 结 果
(Test Results)

No. GPL3J3KO235225L1

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)		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)		
	审核人 (Checked by)		
	批准人 (Approved by)		
	签发日期 (Issued Date)	2021 年 10 月 01 日	

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电话：010-83055000 传真：010-82619629

检 测 结 果
(Test Results)

No. GPL3J3KO235225L1

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)
				A	B	C		
1	压力差 Differential pressure	Pa/cm^2	＜60	1-1	55.7		符合 Pass	EN 14683:2019+ AC:2019(E) 附录 C Appendix C
				1-2	41.4			
				1-3	55.7	50.1		
				1-4	50.4			
				1-5	47.1			
				2-1	45.7			
				2-2	47.3			
				2-3	42.0	47.9		
				2-4	54.1			
				2-5	50.6			
				3-1	56.5			
				3-2	55.1			
				3-3	49.4	51.6		
				3-4	48.8			
				3-5	48.0			
				4-1	58.0			
				4-2	58.8			
				4-3	46.9	51.2		
				4-4	45.9			
				4-5	46.3			
				5-1	58.2			
				5-2	46.1			
				5-3	57.8	52.7		
				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。

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检 测 结 果
(Test Results)

No. GPL3J3KO235225L1

照片 Photo:

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(End of Report)

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