



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 30 Cajas

Cod EAN: 9 6974100420430 - Made in China

UDI-DI Básico: 6974100420430AT4

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

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Uhealth Medical (Beijing) Protective Products Co., Ltd.
1st Floor, Building 2, No. 15, Jingsheng South Fourth
Street, Tongzhou District, Beijing, P.R. China

Trademark:**SRN:**

Not available yet

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN:

Not available yet

Trade name:

Disposable Medical Face Mask

Product Name:

Disposable Medical Face Mask

Product code / Catalogue number:

LHKL-B-1, LHKL-L-1, LHKL-G-1, LHKL-BA-1 (earloop type)
LHKL-TB-1, LHKL-TL-1, LHKL-TG-1 (tie-on type)

Basic UDI

Not available yet

Classification acc. to MDR Ax. VIII:

Class I, rule 1

Applied Standard&Common Specification:

EN 14683:2019 +AC:2019

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

Name and ID of the Notified Body:

N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

General Manager

Legally binding signature, Function

Beijing, China, 30th, Sept, 2021

Place, date



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

Thecnical Declaration

Dated: 01th of October, 2021

We Uhealth Medical (Beijing) Protective Products Co., Ltd. hereby declare that our face mask with the specifications is as below, witch is comercialize by the company Luhepa Internacional, S.L. is according to our folloing item:

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

- **Size:** 17,5 x 9,5 cm +/-0,5cm
- **Layer Weight:** (Raw Material) 20+25+25g
- **Nose Clip:** 11cm
- **Earloop:** 17,5cm
- **Color:** Black
- **BFE:** =>99%

Certificates:

CE Conformity of Declaration (CE DOC): See attachment

Test Report:

EN14683 Type IIR - See attachment

European representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany
CE Registrarion Number: DE/CA61/1M50/139

We declare that our face mask material is **without Graphene, Látex and Fiberglass** in the composition. The Mask is made of Polypropylene



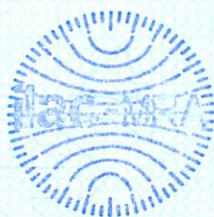
Date: October, 01 th, 2021

General Manager: Cybil Zhai

For and on behalf of
Uhealth Medical (Beijing) products Co., Ltd.
北京联合康力医疗器械有限公司

.....
Authorized Signature(s)

Company stamp and/or legal signature



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	

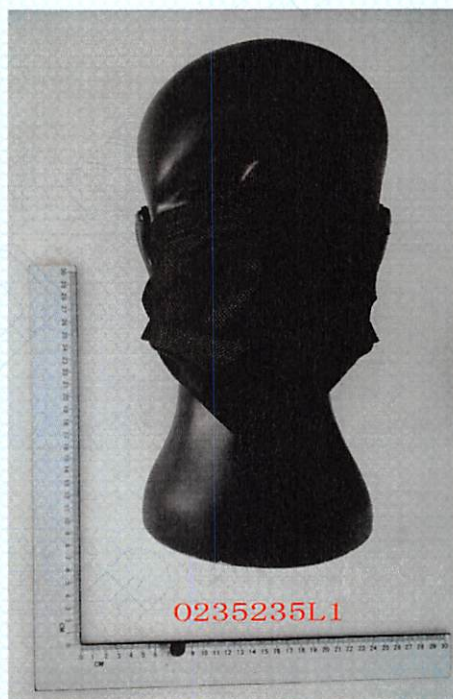
检测结果 (Test Results)

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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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.



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检测结果

(Test Results)

No. GPL3J3KO235225L1

第 1 页, 共 3 页 (page 1 of 3)

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

第 2 页, 共 3 页 (page 2 of 3)

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.								

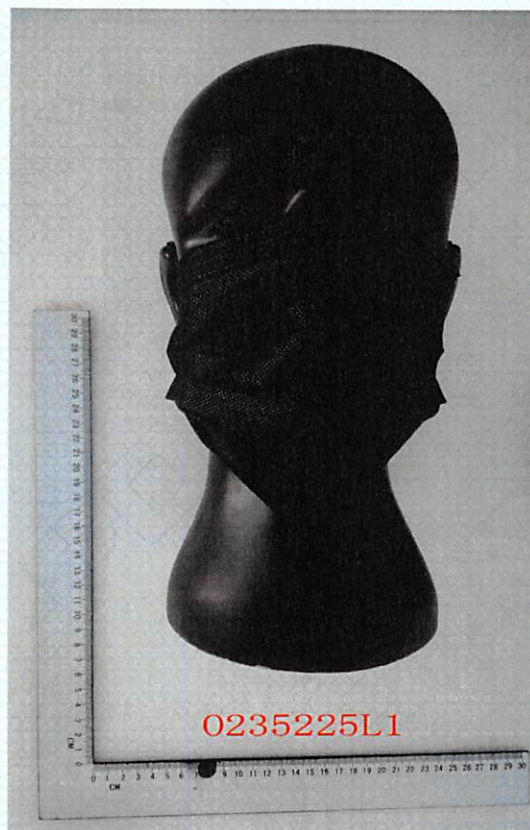
备注 Note: A-试样编号-测试区域编号 Test Specimen number-Test area number; B-每个测试区域的压力差 Differential pressure for each test area; C-每个试样的平均压差 The averaged differential pressure for each test specimen.

检测结果 (Test Results)

No. GPL3J3KO235225L1

第 3 页, 共 3 页 (page 3 of 3)

照片 Photo:



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(End of Report)

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG **General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG**

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika **Form for Medical Devices except In Vitro Diagnostic Medical Devices**

Zuständige Behörde / Competent authority			
Code DE/CA61			
Bezeichnung / Name Regierung von Oberbayern			
Staat / State Deutschland		Land / Federal state Bayern	
Ort / City München		Postleitzahl / Postal code 80534	
Straße, Haus-Nr. / Street, house no. Maximilianstraße 39			
Telefon / Phone +49-89-21760		Telefax / Fax +49-89-21762914	
E-Mail / E-mail medizinprodukteanzeigeverfahren@reg-ob.bayern.de			

Anzeige / Notification			
Registrierdatum bei der zuständigen Behörde Registration date at competent authority		Registriernummer / Registration number 00162389	
Typ der Anzeige / Notification type <input type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change <input type="checkbox"/> Widerrufsanzeige / Notification of withdrawal			
Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn DE/CA61/1M50/139			
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG <input type="checkbox"/> Hersteller / Manufacturer <input type="checkbox"/> Bevollmächtigter / Authorised Representative <input type="checkbox"/> Einführer / Importer <input type="checkbox"/> Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG <input type="checkbox"/> Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV <input type="checkbox"/> Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG			

Anzeigender / Reporting organisation (person)			
	Code DE/0000047823		
	Bezeichnung / Name MedPath GmbH		
	Staat / State Deutschland		Land / Federal state Bayern
	Ort / City München		Postleitzahl / Postal code 80807
	Straße, Haus-Nr. / Street, house no. Mies-van-der-Rohe-Strasse 8		
	Telefon / Phone 089 189174474		Telefax / Fax
	E-Mail / E-mail info@medpath.pro		

Hersteller / Manufacturer			
	Bezeichnung / Name Uhealth Medical (Beijing) Protective Products Co., Ltd.		
	Staat / State CN		
	Ort / City Beijing		Postleitzahl / Postal code 101111
	Straße, Haus-Nr. / Street, house no. 5th Floor, Building 1, Courtyard No.11, Kechuang 14th Street, Economic and Technological Development Area		
	Telefon / Phone +86-10-50927917		Telefax / Fax
	E-Mail / E-mail Jorge.santos@uhealthbj.com, Sales@uhealthbj.com		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG			
	Bezeichnung / Name Zheng Mei c/o MedPath GmbH		
	Staat / State Deutschland		Land / Federal state Bayern
	Ort / City München		Postleitzahl / Postal code 80807
	Straße, Haus-Nr. / Street, house no. Mies-van-der-Rohe-Strasse 8		
	Telefon / Phone 089 189174474		Telefax / Fax 089 5485 8884
	E-Mail / E-mail info@medpath.pro		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	<input type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	<p>Klasse / Class</p> <p>S I</p> <p>£ I - steril / sterile</p> <p>£ I - mit Messfunktion / with measuring function</p> <p>£ I - steril und mit Messfunktion / sterile and with measuring function</p> <p>£ IIa</p> <p>£ IIb</p> <p>£ III</p> <p>£ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012</p> <p>£ Aktives implantierbares Medizinprodukt / Active implantable medical device</p> <p>£ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012</p>
	<p>App (Software auf mobilen Endgeräten) £ ja / yes S nein / no</p>
	<p>Nummer(n) der Bescheinigung(en) / Certificate number(s)</p>
	<p>Handelsname des Produktes / Trade name of the device Disposable Medical Face Mask</p>
	<p>Produktbezeichnung / Name of device</p>
	<p>Nomenklaturcode / Nomenclature code 12-447</p>
	<p>Nomenklaturbezeichnung / Nomenclature term Maske</p>
	<p>Kategoriecode / Category code 10</p>
	<p>Kategorie / Category Produkte zum Einmalgebrauch</p>
	<p>Kurzbeschreibung deutsch / German short description</p>
	<p>Kurzbeschreibung englisch / English short description</p>

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	<input type="checkbox"/> Semikritische Medizinprodukte / Semicritical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B
	<input type="checkbox"/> Kritische Medizinprodukte / Critical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B <input type="checkbox"/> Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures <input type="checkbox"/> Dampfsterilisation / Steam sterilisation <input type="checkbox"/> Gassterilisation / Gas sterilisation <input type="checkbox"/> Strahlensterilisation / Radiation sterilisation <input type="checkbox"/> andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
 I affirm that the information given above is correct to the best of my knowledge.

Ort City	München	Datum Date	2020-07-21
		Name	Zheng Mei
			Unterschrift Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
<div style="background-color: #cccccc; width: 20px; height: 20px; margin-bottom: 5px;"></div> Bearbeiter / Person responsible	<div style="background-color: #cccccc; width: 20px; height: 20px; margin-bottom: 5px;"></div> Telefon / Phone