Ficha Técnica de Producto

Ref. 3500A

Mascarilla Quirurgica Tipo IIR Con Gomas

Luhepa INTERNACIONAL, S.L.

Member of Uhealth Medical Group

Información Técnica:

Modelo Fabricante : LHKL-B-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: AZUL
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°: GOLMOXKC355595L1
Laboratorio Acreditado por CNAS N°: L0412

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 6974100420423- Made in China
UDI-DI Básico: 6974100423500AT4

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

Luhepa Internacional,S.L.
Camino de la Torre, Nave 2 - 45512 PORTILLO DE TOELDO (Toledo)
T. +34 925 678 656 Mail: luhepa@luhepa.es

CIF: B-01985480
Licencia Sanitaria: 8468-PS
Registro Sanitario Alimentario: 39.006740/TO

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 Manufacturer:	CN-MF-000010566
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
SRN Authorized Representative:	DE-AR-000000087
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	6974100423500AT4
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.

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

General Manager

Legally binding signature, Function

Authorized Signature(s)

Beijing, China, 01th, January, 2022

Place, date

Uhealth Medical (Beijing) Protective Produts 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 declarate that our face mask with the specifications is as below, witch is comercialize by the company Luhepa Internacional, S.L. is acording to our follwoing item:

Model Ref. LHKL-B-1 = Ref. 3500A

- **Size:** 17,5 x 9,5 cm +/-0,5cm
- **Layer Weight:** (Raw Material) 20+25+25g
- **Nose Clip:** 11cm
- **Earloop:** 17,5cm
- **Color:** Blue
- **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 declarate 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

PONY 谱尼测试
Pony Testing International Group

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国际互认
检测
TESTING
CNAS L0412

检 测 报 告

(Test Report)

No. GOLMOXKC355595L1

样品名称 (Sample Description)	一次性医用口罩 Disposable Medical 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

声 明
Statement

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This report is invalid without special seal of inspection, cross-page seal and the approver's signatures.

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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。
Tests that can not be repeated and tested shall not be carried out again.

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上海实验室: (021) 64851999 长春实验室: (0431)85150908 石家庄实验室: (0311)85376660 温州实验室: (0577)88271060
青岛实验室: (0532)88706866 大连实验室: (0411)87336618 乌鲁木齐实验室: (0991) 6684186 合肥实验室: (0551)63843474
深圳实验室: (0755)26050909 郑州实验室: (0371)69350670 呼和浩特实验室: (0471) 3450025 广州实验室: (020) 89224310
天津实验室: (022) 23607888 西安实验室: (029) 89608785 杭州实验室: (0571)85806807 厦门实验室: (0592)5568048
苏州实验室: (0512)62997900 太原实验室: (0351) 7555762 宁波实验室: (0574)87977185 成都实验室: (028) 87702708

检 测 结 果
(Test Results)

No. GOLMOXKC355595L1

样品名称 (Sample Description)	一次性医用口罩 Disposable Medical Face Mask	样品规格 (Sample Specification)	17.5cm*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)	2020-08-17	生产日期或批号 (Manufacturing Date or Lot No.)	2020.7.30 20200730
检测日期 (Test Date)	2020-08-17~2020-08-26	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)	口罩颗粒物过滤效率及气流阻力测试仪 等 Respirator particle filtration efficiency and airflow resistance tester etc.		
备注 (Note)	1.型号：LHKL-B-I Model：LHKL-B-I 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：BS EN 14683:2019（IIR 型） Limit Standard：BS EN 14683:2019(Type IIR)		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)	张钊	
	审核人 (Checked by)	乙刘	
	批准人 (Approved by)	孙兆增	
	签发日期 (Issued Date)	2020 年 08 月 26 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. GOLMOXKC355595L1

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	98.62			符合 Pass	BS EN 14683:2019 附录 B Appendix B
				98.97				
				98.79				
				98.75				
				98.92				
2	压力差 Differential pressure	Pa/cm²	<60	A	B	C	符合 Pass	BS EN 14683:2019 附录 C Appendix C
				1-1	32.9			
				1-2	25.6			
				1-3	27.0	28.8		
				1-4	30.3			
				1-5	28.1			
				2-1	27.8			
				2-2	23.3			
				2-3	26.1	24.0		
				2-4	22.6			
				2-5	20.3			
				3-1	22.0			
				3-2	19.9			
				3-3	25.6	23.4		
				3-4	24.1			
				3-5	25.2			
				4-1	27.8			
				4-2	28.4			
				4-3	26.8	28.6		
				4-4	35.5			
				4-5	24.5			
				5-1	30.0			
				5-2	33.1			
				5-3	28.2	28.0		
				5-4	23.1			
				5-5	25.7			

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
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电话：010-83055000 传真：010-82619629

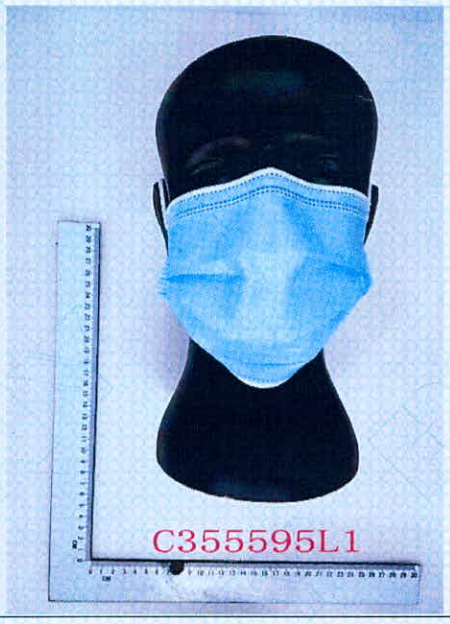
检 测 结 果
(Test Results)

No. GOLMOXKC355595L1

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)
3	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
4	微生物洁净度 Microbial cleanliness	cfu/g	≤30	＜1	符合 Pass	BS EN 14683:2019 附录 D Appendix D
				＜1		
				＜1		
				＜1		
				＜1		

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。

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
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电话：010-83055000 传真：010-82619629

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00311621

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 £ Erstanzeige / Initial notification S Änderungsanzeige / Notification of change £ 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 £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ 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 £ 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 £ 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		
	S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class S I £ I - steril / sterile £ I - mit Messfunktion / with measuring function £ I - steril und mit Messfunktion / sterile and with measuring function £ IIa £ IIb £ III £ 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 £ Aktives implantierbares Medizinprodukt / Active implantable medical device £ 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
	App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Disposable Medical Face Mask**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code **12-447**
	Nomenklaturbezeichnung / Nomenclature term **Maske**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	£ Semikritische Medizinprodukte / Semicritical medical devices £ Gruppe A / Group A £ Gruppe B / Group B
	£ Kritische Medizinprodukte / Critical medical devices £ Gruppe A / Group A £ Gruppe B / Group B £ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures £ Dampfsterilisation / Steam sterilisation £ Gassterilisation / Gas sterilisation £ Strahlensterilisation / Radiation sterilisation £ 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			
	Bearbeiter / Person responsible		Telefon / Phone