

## Mascarilla Quirúrgica Tipo IIR Con Gomas

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 Nº: GOLMOXKC355595L1

Laboratorio Acreditado por CNAS Nº: L0412

Eficiencia de Filtración Bacteriana	Respirabilidad/Presión Diferencial	Limpieza Microbiana/Carga Biológica	Presión de Resistencia a Salpicaduras
$\geq 98\%$	$< 60\%$	$\leq 30$ UF/g	$\geq 16$

### 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 5º y 35º. 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 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

Beijing, China, 01th, January, 2022

Legally binding signature, Function

Place, date

Authorized Signature(s)



# 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 folloving 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 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. 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

## 声明 Statement

1. 本报告无检验检测专用章、报告骑缝章和批准人签章无效。  
This report is invalid without special seal of inspection, cross-page seal and the approver's signatures.
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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.
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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
青岛实验室: (0532)88706886	大连实验室: (0411)87336618	乌鲁木齐实验室: (0991) 6684186
深圳实验室: (0755)26050909	郑州实验室: (0371)69350670	呼和浩特实验室: (0471) 3450025
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		合肥实验室: (0551)63843474
		广州实验室: (020) 89224310
		厦门实验室: (0592)5568048
		成都实验室: (028) 87702708

## 检测结果 (Test Results)

No. GOLMOXKC355595L1

第 1 页, 共 3 页 (page 1 of 3)

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) 谱尼测试集团 PONY TESTING INTERNATIONAL GROUP CO.,LTD 检验检测专用章	编制人 (Edited by)	张利	
	审核人 (Checked by)	王明	
	批准人 (Approved by)	孙兆增	
	签发日期 (Issued Date)	2020 年 08 月 26 日	

## 检测结果

(Test Results)

No. GOLMOXKC355595L1

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	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/cm <sup>2</sup>	<60	A	B	C	符合 Pass	BS EN 14683:2019 附录 C Appendix C
				1-1	32.9	28.8		
				1-2	25.6			
				1-3	27.0			
				1-4	30.3			
				1-5	28.1			
				2-1	27.8	24.0		
				2-2	23.3			
				2-3	26.1			
				2-4	22.6			
				2-5	20.3			
				3-1	22.0	23.4		
				3-2	19.9			
				3-3	25.6			
				3-4	24.1			
				3-5	25.2			
				4-1	27.8	28.6		
				4-2	28.4			
				4-3	26.8			
				4-4	35.5			
4-5	24.5							
5-1	30.0	28.0						
5-2	33.1							
5-3	28.2							
5-4	23.1							
5-5	25.7							

## 检测结果 (Test Results)

No. GOLMOXKC355595L1

第 3 页, 共 3 页 (page 3 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)
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:



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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

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

<b>Anzeige / Notification</b>			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority		Registriernummer / Registration number <b>00162389</b>
	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 <b>DE/CA61/1M50/139</b>		
	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		

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

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

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

<b>Vertreter / Deputy (optional)</b>	
	Bezeichnung / Name
	Telefon / Phone
	Telefax / Fax
	E-Mail / E-mail
	S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change

<b>Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)</b>	
	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) <span style="float: right;">£ ja / yes    S nein / no</span>
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device <b>Disposable Medical Face Mask</b>
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code <b>12-447</b>
	Nomenklaturbezeichnung / Nomenclature term <b>Maske</b>
	Kategoriecode / Category code <b>10</b>
	Kategorie / Category <b>Produkte zum Einmalgebrauch</b>
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description

<b>Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)</b>	
	<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	<b>München</b>	Datum Date	<b>2020-07-21</b>
		Name	<b>Zheng Mei</b>
			Unterschrift Signature

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