



Ref. 3500A — Mascarilla Quirúrgica Tipo IIR, Con Gomas de Ajuste

Modelo Fabricante: LHKL-B-1



INFORMACIÓN TÉCNICA:

- Mascarilla Quirúrgica Tipo IIR NR, fabricada con 3 capas de tela no tejida y tejido filtrante.

1ª Capa: Tela No Tejida 25 grs

Clip Nariz: 8,2 cm

2ª Capa: Melt-Blown 25 grs

Gomas: 19 cm

3ª Capa: Tela No Tejida 20 grs

Color: Azul

Medidas: 17,5x9,5 cm

-Tira nasal moldeable fabricada en Acero + PP y con dos gomas de ajuste.

- Mascarilla y Gomas libres de látex y fibra de vidrio, no produce irritaciones en la piel.

- Las Mascarillas Ref.3500A responden a las exigencias de la norma **EN 14683:2019+AC2019**.

- Número de Ensayo GOLMOXKC355595L1., Laboratorio acreditado por CNAS N°: L0412

- Las Mascarillas Ref.3500A son conformes el **Reglamento UE 2017/745** relativo a los productos sanitarios (MRD). Clase I.

- **Respirabilidad/Presión Diferencia:** <60%

- **Limpieza Microbiana/Carga Biológica:** <= 30 UFC/g

- **Presión de Resistencia a las Salpicaduras:** >=16

INFORMACIÓN LOGÍSTICA:

Etiquetado conforme a la Norma 14683:2019+AC:2019

Presentación:

- Estuches Dispensadores de 50 unid

- Embalajes de 2.000 unidades

Medidas Cajas: 49,5x39x43

Cod. EAN: 7 784690 62258

Almacenar en el embalaje original en un lugar seco, limpio, temperaturas oscilantes entre 5º y 30º. No exponer a la luz solar

INSTRUCCIONES DE USO:

- Mascarilla con una vida útil de hasta 8 horas bajo unas condiciones controladas de laboratorio, el fabricante recomienda un uso máximo de hasta 4 horas. Producto No reutilizable.

- Instrucciones para una correcta Colocación:

1.- Lavarse las manos antes de manipular la mascarilla.

2.- Tocar únicamente la goma de la mascarilla.

3.- Colocar la mascarilla sobre la nariz y boca.

4.- Pasar las gomas por detrás de las orejas.

5.- Ajustar adecuadamente la tira nasal a la nariz.

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

EU DECLARATION OF CONFORMITY

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

Manufacturer:

Uhealth Medical (Beijing) Protective Products Co., Ltd.
Room 128, Floor 1, Building 2, No.11 Courtyard,
Kechuang 14th Street, Economic and Technological
Development Zone, 101111 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-F-1) LHKL-L-1, LHKL-G-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.

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

Legally binding signature, Function

Authorized Signature(s)

Beijing, China April 27th, 2020

Place, date



Uhealth Medical (Beijing) Products Co., Ltd.

Add.: No.1 Military-Civil Integration Industrial Park, Daxing District, Beijing, China

3-Ply facemask (Ear loop)

Specification:

Size	Nose Clip	Ear loop	Color	Raw material	BFE
17.5x9.5cm±0.5cm	11cm	17.5cm	blue	25gsm+25gsm+20gsm	≥99%
Packing: 50pcs/box, 40box/carton					

Certificates:

CE Conformity of Declaration (CE DOC): See attachment

Test report: see attachment

- EN14683 TYPE IIR (see attachment)

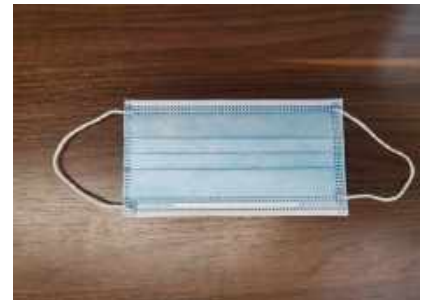
Europe representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse8 80807 Munich, Germany

CE Registration number: DE/CA61/1M50/139

Picture:





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

5th Floor, Building 1, Courtyard No.11, Kechuang 14th Street, Economic and Technological Development Area, Beijing, China

Declaration

Dated: 16th of April, 2021

To whom may concern:

We Uhealth Medical (Beijing) Products Protective Co., Ltd. Hereby declare that our facemask with the specification is as below, which was sold to company of LUHEPA INTERNACIONAL,S.L:

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

- Earloop
- 20+25+25gsm
- 9.5x17.5cm
- BFE≥99%
- EN14683:2019+AC:2019 Type IIR

We declare that our face mask material is **without Graphene composition**, the face mask is made of Polypropylene. Pls kindly note it, which will be not harmed to people.

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

General Manager: Cybil Zhai

Sign and stamp

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)



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

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北京实验室: (010) 83055000	武汉实验室: (027) 83997127	哈尔滨实验室: (0451) 58627755
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) 88706866	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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		温州实验室: (0577) 88271060
		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)		
	编制人 (Edited by)	张利	
	审核人 (Checked by)	王强	
	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 ²	<60	A	符合 Pass	BS EN 14683:2019 附录 C Appendix C		
				B			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

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 18.05.2020		Registriernummer / Registration number DE/CA61/1M50/139
	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		
	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. Room 128, Floor 1, Building 2, No.11 Courtyard, Kechuang 14th Street, Economic and Technological Development Zone		
	Telefon / Phone +86-18911987264		Telefax / Fax
	E-Mail / E-mail 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 E 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)	
	<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	2020-04-28
		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 Sachgebiet 53.2 Pharmazie	Telefon / Phone 089-2176-0