FICHA TÉCNICA

PROLIMAX HIGIENE INDUSTRIAL, S.L.

Ref: 64703

Mascarilla Polipropileno Azul 3 Capas Alto Riesgo Con Gomas

CARACTERÍSTICAS DEL PRODUCTO

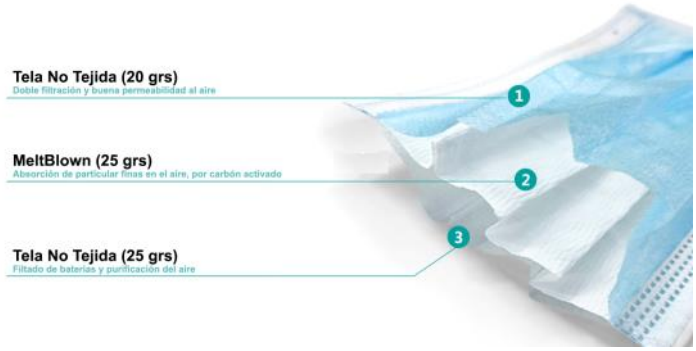
-Mascarilla de Polipropileno Rectangular de 3 capas, con 3 pliegues que provocan un mejor acople anatómico. Con tira moldeable en la parte superior para provocar una mejor sujeción nasal y con elástico de ajuste para un mejor acople en ambos pabellones auditivos.

INSTRUCCIONES

-Producto de UN SOLO USO, no reutilizar.
-Almacenar siempre en el embalaje original, en un lugar seco y a temperaturas oscilantes entre –2º y +50º (se aconseja siempre entre +5º y +30º). No exponer directamente a la luz solar.

PROPIEDADES FÍSICAS

- Materia prima Primera Capa: Polipropileno (PP) con una densidad de 20 grs/m^3.
- Materia prima Segunda Capa: MeltBlown con una densidad de 25 grs/m^3.
- Materia prima Tercera Capa: Polipropileno (PP) con una densidad de 25 grs/m^3.
- Color: AZUL
- Medidas: 17,5x9,5 cm
- Elástico de ajuste suaves para un ajuste confortable en ambos pabellones auditivos.



PRESENTACIÓN Y LOGÍSTICA:

- Presentación: 40 estuches con 50 mascarillas. Total Caja: 2.000 Mascarillas
- Caja exterior con descripción completa, pictogramas informativos y código de barras
- Medidas Caja: 49,5x39x43
- Referencia Prolimax: 64703
- Código de Barras (EAN): 7 784690 62258

Cajas por Palet	Estuches por Palet
24	960

NORMATIVAS

- Reglamento (EU) 2017/745 Relativa a Productos sanitarios (MDR). Producto Sanitario Calse I

- EN-14683:2019+AC:2019 Norma mascarillas quirurgica de Eficiencia de Filtración Bacteriana >=98%
Transpirabilidad: < 60%
Resistencia a la salpicaduras >= 16
Mascarilla Quirúrgicas Tipo IIR
Certificado Pony Testing Internacional Group Nº: BOLEB9ZT014847L1

- Producto 100 % Libre de Látex

USOS

Mascarilla de protección para uso general, indicada especialmente para el uso en el sector Sanitario, Medico Hospitalario, Equipamiento Laboratorio, Químico, Estética, Alimentación, Limpieza, Pintura, Industria y Agricultura.

PROLIMAX HIGIENE INDUSTRIAL,S.L.
CIF: B-45632767
C/ Jardines, 7 - CP:45525 — BARCIENCE (Toledo)
Tlf: 925 779 507 - Fax: 925 771 364
mail: info@prolimax.es

R.G.S.A Importador fuera de la CEE 39.03909/TO
Licencia Importador Producto Sanitario 5971-PS

Atención al cliente
925 779 507
www.prolimax.es

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 II (already have)
- EN14683 TYPE IIR (will updated on 27th of May)

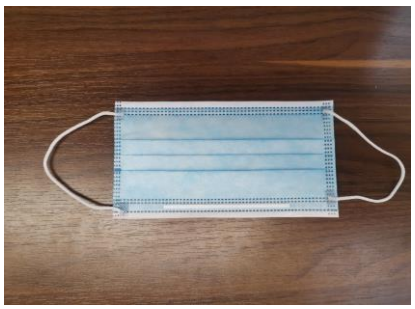
Europe representative:

MedPath GmbH

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

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

Picture:



Website: www.uhealthbj.com Email: sales@uhealthbj.com Tel.: 0086 10 8792 7887

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
Trade name / Trademark:	N. A.
SRN:	Not available yet
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse8 80807 Munich, Germany
SRN:	Not available yet
Product Name:	Disposable Medical Face Mask
Trade name:	N. A.
Model:	LHKL-B-1, LHKL-L-1, LHKL-G-1, LHKL-TB-1, LHKL-TL-1, LHKL-TG-1
Basic UDI	N. A.
Classification acc. to MDR Ax. VIII:	Class I, rule 1
Applied Common Specification:	17.5*9.5cm
Conformity assessment procedure:	N. A.
CE certificate No.:	N.A.
Name of the Notified Body:	N.A.
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.
北京联合康力医疗防护用品有限公司

General Manager

Legally binding signature, Function

Authorized Signature(s)

Beijing, April, 27th, 2020

Place, date

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00303766

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 S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ 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 £ 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. **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 £ 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 **2020-04-28**

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**

PONY 谱尼测试
Pony Testing International Group

JCFM-1

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关注谱尼测试

CMA
160920340809

检 测 报 告
(Test Report)

No. BOLEB9ZT014847L1

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
www.ponytest.com

声 明
Statement

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PONY 谱尼测试
Pony Testing International Group

检测结果
(Test Results)

No.BOLEB9ZT014847L1

样品名称 (Sample Description)	一次性医用口罩 Disposable Medical Face Mask	样品规格 (Sample Specification)	规格 Specification: 17.5*9.5cm 型号 Model：LHKL-B-1
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)	2020-05-14	生产日期或批号 (Manufacturing Date or Lot No.)	生产日期 Manufacturing Date：2020/03/25 生产批号 Manufacturing Lot No.：2020/03/25
检测日期 (Test Date)	2020-05-14~2020-05-28	样品等级 (Sample Grade)	——
样品数量 (Sample Quantity)	80 个 80pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	正常 Normal	检测环境 (Test Environment)	符合要求 (To meet the requirements)
检测项目 (Test Items)	见下页 See the next page		
检测方法 (Test Methods)	见下页 See the next page		
所用主要仪器 (Main Instruments)	电热恒温培养箱 Electric Heating Constant Temperature Incubator、细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc.		
备注 (Note)	限值标准 Limit Standard：EN 14683：2019 生产单位 Production：北京联合康力医疗防护用品有限公司 Uhealth Medical (Beijing) Protective Products Co.,Ltd. 受检单位 Inspection：北京联合康力医疗防护用品有限公司 Uhealth Medical (Beijing) Protective Products Co.,Ltd. 以上样品信息由委托单位提供 The information of above sample was provided by the applicant.		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)		
	审核人 (Checked by)		郭惠
	批准人 (Approved by)		戴晓
	签发日期 (Issued Date)		2020-05-28

检测结果
(Test Results)

No.BOLEB9ZT014847L1

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	限值 (Limit)			检测结果 (Test Results)		检测方法 (Test Methods)
		I 型 Type I	II型 Type II	IIR 型 Type IIR			
T014847L1 一次性医用口罩 Disposable Medical Face Mask	细菌过滤效率 (BFE)，% Bacterial filtration efficiency(BFE)	≥95	≥98	≥98	No.1	99.7	EN 14683：2019
					No.2	99.8	
					No.3	99.8	
					No.4	99.8	
					No.5	99.7	
	压力差，Pa/cm² Differential pressure	<40	<40	<60	20.9		EN 14683：2019
	抗溅压力，kPa Splash resistance pressure	/	/	≥16.0	>16.0		EN 14683：2019
	微生物清洁度，cfu/g Microbial cleanliness	≤30	≤30	≤30	<1		EN 14683：2019

样品编号和照片（Sample Number and Photo）：

仅对报告照片中的样品负责
Pony authenticate the photo on original report only

————以下空白————
(End of Report)