FICHA TÉCNICA

GRASLIM, S.L.

Ref: 64703 — Modelo: LHKL-B-1

Mascarilla Polipropileno Quirúrgica Azul 3 Capas Con Gomas

CARACTERÍSTICAS DEL PRODUCTO

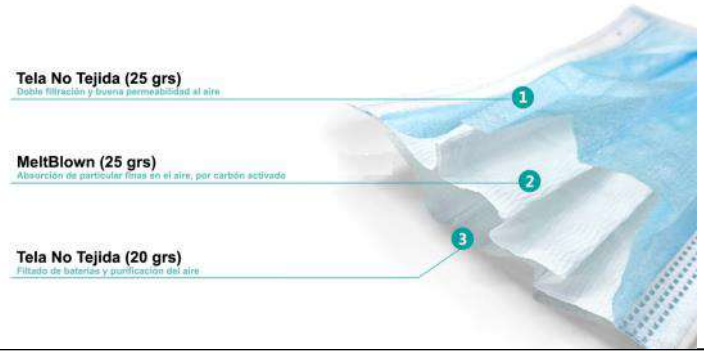
-Mascarilla de Polipropileno Rectangular de 3 capas, con 3 pliegues que provocan un mejor acople anatómico. Con tira moldeable en la parte superior para provocar una mejor sujeción nasal y con elástico de ajuste para un mejor acople en ambos pabellones auditivos.

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.
-Tiempo máximo de uso 4 horas

PROPIEDADES FÍSICAS

- Materia prima Primera Capa: Polipropileno (PP) con una densidad de 25 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 20 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: 64703
- Código de Barras (EAN): 7 784690 62258

Cajas por Palet	Estuches por Palet
30	1200

NORMATIVAS

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

- EN-14683:2019+AC:2019 Norma mascarillas Quirúrgica de Eficacia de Filtración Bacteriana >=98%
Respirabilidad/Presión Diferencial: < 60%
Presión de Resistencia a las Salpicaduras: >=16
Limpieza Microbiana/Carga Biológica: <= 30 UFC/g
Mascarilla Quirúrgicas Tipo IIR
Certificado Pony Testing International Group Nº: GOLMOXKC355595L1
Laboratorio Acreditado por CNAS Nº: L0412

- Ensayo Específico COVID-19 Ensayo realizado por Laboratorio CITEVE, con número 10010L/2020 –1 relativo a la mascarillas y su uso ante COVID-19. Basado en la permeabilidad en mascarillas de un solo uso EN ISO 9237:1995 y la retención de particular MI 142/00. Resultados conformes en mascarillas Nivel 2 para uso profesional y conforme a las mascarillas de Cirugía.

- Producto 100 % Libre de Látex y Fibra de Vidrio.

CE LATEX FIBRA DE VIDRIO

Graslim
C/ Albert Einstein, 7 - 45500 Torrijos (Toledo)
Telf. 925770435 - info@graslim.com

ÚLTIMA REVISIÓN
04/01/2021

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:	Uhealth 联合康力
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.
北京联合康力医疗防护用品有限公司

Yuri Zhao General Manager

Legally binding signature, Function

Authorized Signature(s)

Beijing China April 27th, 2020

Place, date

Uhealth Medical (Beijing) Products Co., Ltd.
Add. No.11, 14th Ke Chuang Rd. Economic Development Area
Rm 128, Building 2, Beijing, China 100176

Declaration

Dated：22th of July, 2020

To whom may concern:

We **Uhealth Medical (Beijing) Products Co., Ltd.** Hereby declare that our facemask with the specification is as below:

Model Ref: LHKL-B-1 =LHKL-F-1

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

which was sold to company of **PROLIMAX HIGIENE INDUSTRIAL, S.L.** with the face mask **Model Ref: 64703** is same.

We kindly hope that you could understand with many thanks!

Uhealth Medical (Beijing) Products Co., Ltd.

General Manager: Cybil Zhai

Sign and stamp Cybil

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)

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)

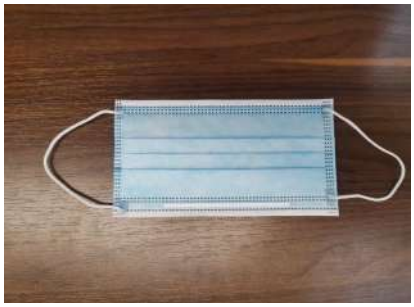
Europe representative:

MedPath GmbH

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

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

Picture:



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

PONY 谱尼测试
Pony Testing International Group

扫微信二维码
关注谱尼测试

CMA 160000343608

ilac-MRA CNAS 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

PONY 谱尼测试
Pony Testing International Group

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.

2. 本报告页面所使用“PONY”、“谱尼”字样为本单位的注册商标，其受《中华人民共和国商标法》保护，任何未经本单位授权的擅自使用和仿冒、伪造、变造“PONY”、“谱尼”商标均为违法侵权行为，本单位将依法追究其法律责任。
The pattern and characters of "PONY" and "谱尼" used in this report are protected by the trademark law of the People's Republic of China. Any unauthorized usage, counterfeit, forgery and alteration of trademarks of "PONY" and "谱尼" are the violations of the law. The PONY has the right to pursueall legal liabilities of the subject of the delict.

3. 委托单位对报告数据如有异议，请于报告完成之日起十五日内（初级农产品报告请于报告收到之日起五日内）向本单位书面提出复测申请，同时附上报告原件并预付复测费。
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.

6. 委托单位对样品的代表性和资料的真实性负责，否则本单位不承担任何相关责任。
The applicant should undertake the responsibility for the provided samples' representativeness and document authenticity. Otherwise, PONY has not any relevant responsibilities.

7. 本报告仅对所测样品负责，报告数据仅反映对所测样品的评价，对于报告及所载内容的使用、使用所产生的直接或间接损失及一切法律后果，本单位不承担任何经济和法律责任。
This report is only responsible for the provided sample. The test results only represent the evaluation of the tested sample. PONY will not be responsible for any economical or legal liability generated from direct or indirect usage of the test report.

8. 本单位有权在完成报告后按规定方式处理所测样品。
PONY has the right to dispose the tested sample by rules, after approval of the test report.

9. 本单位保证工作的客观公正性，对委托单位的商业信息、技术文件等商业秘密履行保密义务。
PONY assures objectivity and impartiality of the test, and fulfills the obligation of confidentiality for applicant's commercial information, and technique document.

10. 本报告私自转让、盗用、冒用、涂改，未经本单位批准的复制（全文复制除外）或以其它任何形式的篡改均属无效，本单位将对上述行为严究其相应的法律责任。
The report is invalid in case of illegal transfer, embezzlement, imposture, modification or any altering, reproducing except in full, without approval of PONY. PONY shall investigate and affix the applicant's legal liability accordingly.

▲防伪说明(Anti-counterfeiting Description):

(1) 报告编号是唯一的;
The test report has exclusive report code.

(2) 报告采用特制防伪纸张印制,纸张表面带有"PONY"防伪纹路，该防伪纹路不支持复印，即复制件不会带有"PONY"防伪纹路。
The test report is printed by anti-copying paper whose surface shows "PONY" security print with specific anticounterfeiting technique. Security print will disappear after copying. Duplicates are not expected to give "PONY" security print under any circumstances.

全国服务热线
400-819-5688
WWW.PONYTEST.COM

扫描二维码
关注谱尼测试微信
公众号PONY4008195688

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 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

PONY 谱尼测试
Pony Testing International Group

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)	之为	
	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　电话：010-83055000 传真：010-82619629
检测地址：北京市海淀区锦带路 66 号院 1 号楼

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
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

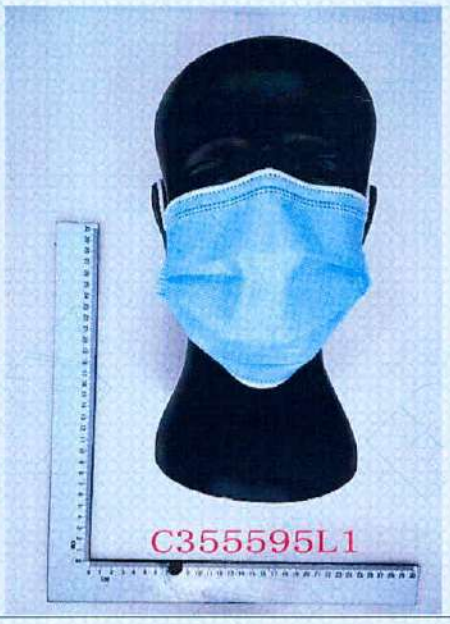
检 测 结 果
(Test Results)

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)
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
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

Centro Tecnológico
das Indústrias Têxtil
e do Vestuário
de Portugal

RELATÓRIO DE ENSAIOS
Nº 10010L/2020 - 1

LABORATÓRIOS - V.N.FAMALICÃO

L0059 Ensaios

À Firma
PROLIMAX HIGIENE INDUSTRIAL, S.L.
C/JARDINES, 7 TOLEDO
BARCIENCE
45525- BARCIENCE TOLEDO ESPANHA

Entrada: 9341/2020 **Data de Recepção das Amostras :** 2020/05/26

Observações

Grupos de Ensaios
Máscaras -Ficha técnica CITEVE 1/04/2020

N. Amostras - V/Referência
13328/2020 - Ref. 64703

Ensaios Requeridos
Projeto COVID-19

Conformidade com as especificações
Ver última página

- Os ensaios foram realizados entre a data 2020/05/26 e 2020/06/09.

V.N.FAMALICÃO, 22 de Junho de 2020

COORDENADOR
DO LABORATÓRIO

(Engª Ana Paula Fonte)

NOTAS:
- Os resultados deste relatório foram obtidos segundo os procedimentos descritos no manual da Qualidade do CITEVE e referem-se apenas às amostras submetidas a ensaios, acima referenciadas.
- O relatório de ensaios não pode ser parcialmente reproduzido sem autorização do CITEVE.
- Os ensaios assinalados com * não estão incluídos no âmbito da acreditação deste laboratório
- l.q - limite de quantificação l.d. - limite de detecção n.d. - não detectado
- As amostras são armazenadas durante 6 meses, após a data de entrada, com exceção dos produtos químicos que são armazenadas por um mês.

LABORATÓRIOS - V.N.FAMALICÃO

No. da Amostra	**V/ Referência**	**Descrição da Amostra**
13328 /2020	Ref. 64703	5 máscaras clínicas faciais de uso único

Ensaio/Norma: ***PERMEABILIDADE AO AR / EN ISO 9237:1995***

Resultados

Valor médio (l/(m2.s) ou mm/s):	64
Caudal médio de ar (l/min):	8

Requisitos mínimos:
- Superior ou igual a 8 l/min

Nota: Os valores de requisitos mínimos são baseados na caracterização de máscaras cirúrgicas certificadas pela norma EN 14683: 2019 tipo I

Condições de Ensaio

Número de provetes testados - 4
Área testada - 20 cm2
Pressão utilizada (Pa) - 40
Ambiente condicionado:
20+/-2ºC e 65+/-4% H.R.

Ensaio/Norma: **** CONFORMIDADE DE CONCEÇÃO / MI***

Resultados

A peça com o clipe nasal fixo apresenta conformidade de conceção.

Ensaio/Norma: **** AVALIAÇÃO DA RETENÇÃO DE PARTÍCULAS / MI 142/00***

Resultados

PRC (superior ou igual a 3 µm) (%) -	100
PRC (0,5 µm a 0,7 µm) (%) -	89

Requisitos mínimos:

Máscaras nível 2, tipo I (cirúrgica):
PRC (superior ou igual a 3 µm)
- Superior ou igual a 95%
PRC (0,5 µm a 0,7 µm)
- Superior ou igual a 35%

LABORATÓRIOS - V.N.FAMALICÃO

Máscaras nível 2, para profissionais em contacto com o público:
PRC (superior ou igual a 3 µm)
- Superior ou igual a 90%

Máscaras nível 3, para população em geral:
PRC (superior ou igual a 3 µm)
- Superior ou igual a 70%

Nota: Os valores de requisitos mínimos são baseados na caracterização de máscaras cirúrgicas certificadas pela norma EN 14683: 2019 tipo I

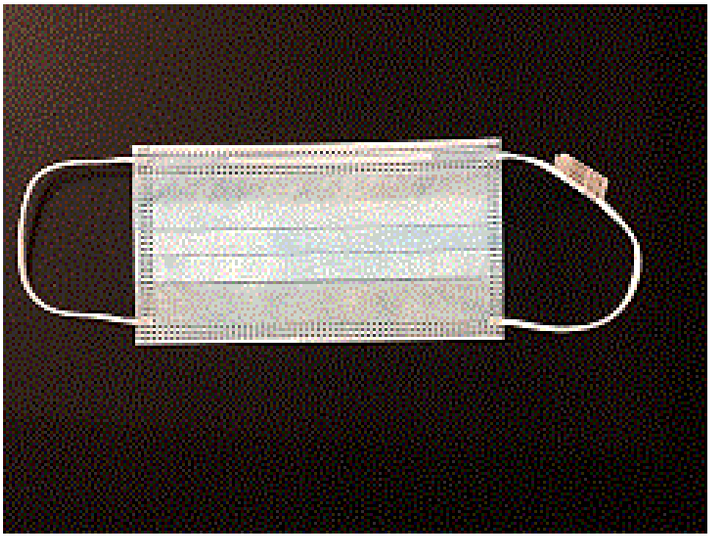
Condições de Ensaio

Velocidade do ar: 28,3 l/min
Tempo de ensaio: 1 min
MPS: 0,6 µm a 0,7 µm
PCR= capacidade de retenção de partículas (%)
MPS= tamanho médio de partículas

LABORATÓRIOS - V.N.FAMALICÃO

Conformidade com as especificações

A máscara testada (amostra 13328/2020) cumpre os requisitos mínimos para máscaras nível 2 para profissionais em contacto com o publico, uso único de acordo com a ficha técnica do CITEVE em vigor.
A máscara testada (amostra 13328/2020) cumpre os requisitos mínimos para máscaras cirurgica TIPO I de acordo com a ficha técnica do CITEVE em vigor.
O folheto informativo deve conter a informação sobre o nivel 2, composição de todas as camadas e nº do relatorio do CITEVE bem como informação sobre a utilização.



Entrada 9341_Amostra 13328

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**