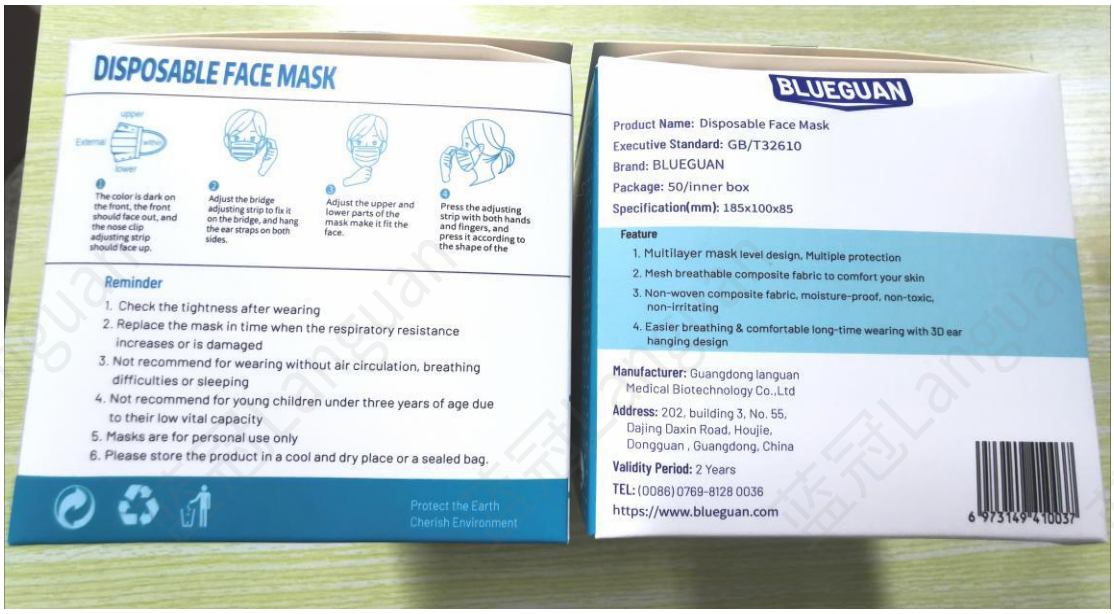
蓝冠 一次性民用口罩----资料



检验报告

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

CMA 201519073OZ

AL 2018(粤)质监认字024号

检 验 报 告

TEST REPORT

第 1 页，共 3 页

报告编号：WT204019876

委 托 单 位 ： 广东蓝冠医疗生物科技有限公司

委托单位地址 ： 广东省东莞市厚街镇大迳大新路55号3号楼202室

样 品 名 称 ： 一次性防护口罩

型号/规格/等级： ----------

检 验 类 别 ： 送样检验

检 验 地 点 ： 龙华实验基地

深圳市计量质量检测研究院
（检验检测专用章）

批准人： 何行月

签发日期：2020年04月09日

签名 ： 何行月

深圳市计量质量检测研究院 Shenzhen Academy of Metrology & Quality Inspection http://www.smq.com.cn

电子邮件(E-mail)：kfzx@smq.com.cn CMA证书附件编号(CMA No.)：201571907302 & 201719001402

龙华实验基地：深圳市龙华区民治大道民康路北114号 查询电话：0755-27528955 传真：0755-27528707 邮编：518131

Longhua Experimental Base：No.114, Minkang North Road, Minzhi Avenue, Longhua District, Shenzhen Tel:0755-27528955

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

报告编号：WT204019876

样品信息：

样品名称： 一次性防护口罩
商标： ----------
型号/规格/等级： ----------
样品编/批号： ----------
生产日期： ----------
生产单位： 广东蓝冠医疗生物科技有限公司
生产单位地址： 广东省东莞市厚街镇大迳大新路55号3号楼202室
样品数量： 50个　　抽样基数： ----------
抽样地点： ----------
抽样人员： ----------
检前样品描述： 正常。

客户信息：

委托单位： 广东蓝冠医疗生物科技有限公司
委托单位地址： 广东省东莞市厚街镇大迳大新路55号3号楼202室
委托单位电话： 13025495299
邮政编码： ----------
受检单位： ----------

检验信息：

委托日期： 2020年04月08日　　委托单号： 8226591
检验类别： 送样检验　　获样方式： 送样
检验日期： 2020年04月08日 至 2020年04月09日
检验环境条件： （18～25）℃ （30～70）%RH
判定依据： GB/T32610-2016
检测依据： GB/T7573-2009等相关方法标准见附页

检验结论：

检验结果见附页。

主检： 廖惠萍　　审核： 刘石磊

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

报告编号：WT204019876　　

检 验 项 目	方 法 标 准	标 准 要 求	实 测 结 果	单项结论
1.色牢度（级） (GB/T32610-2016)				符合
耐摩擦	GB/T29865-2013			
干摩		≥4	4-5	
湿摩		≥4	4-5	
2.甲醛含量 (mg/kg) (GB/T32610-2016)	GB/T2912.1-2009	≤20	未检出(方法检出限为20)	符合
3.pH值 (GB/T32610-2016)	GB/T7573-2009	4.0～8.5	6.7 (萃取介质:氯化钾溶液)	符合

以下空白

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 25th, 2020

Certificate of Compliance

No. 0B200331.GBMDC47

Certificate's Holder: Guangdong Blueguan Medical Biotechology Co., Ltd.
202, Building 3, No. 55, Dajing Daxin Road, Houjie, Dongguan, Guangdong, China.

Certification ECM Mark: ENTE CERTIFICAZIONE MACCHINE – European Conformity – SAFETY COMPLIANCE MARK – Type Approved

Product: Disposable Face Mask (Non sterile)

Model(s): Ear-Hung Mask

Verification to: Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 31 March 2020

Expiry date: 30 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

FDA

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

GUANGDONG LANGUAN MEDICAL BIOTECHNOLOGY CO.,LTD
202, building 3, No. 55, Dajing Daxin Road, Houjie,,
dongguan, Guangdong, 523000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10068118

Listing No.	Product Code:	Device Name:
D387686	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, " Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration, UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

UCL

UCL-REGSERVICE INC.
602 ROCKWOOD ROAD,WILMINGTON,
NEW CASTLE DE 19802 USA

For and on behalf of
UCL-REG SERVICE INC.

Authorized Signature(s)

Cert. No.: M20481
Issued Date: 8 April 2020
Expiration Date: 31 December 2020

莫 森 检 测 报 告

PPE TEST REPORT

Report No.: MOS2020329965S

Client company	:	**Guangdong blueguan Medical Biotechology CO., Ltd**
Client address	:	**202, building 3, No. 55, Dajing Daxin Road, Houjie, Dongguan, Guangdong**
Manufacturer	:	**Guangdong blueguan Medical Biotechology CO., Ltd**
Address	:	**202, building 3, No. 55, Dajing Daxin Road, Houjie, Dongguan, Guangdong**

Report on the submitted samples said to be:

Sample Name	:	**disposable face mask**
Trade Mark	:	**Blueg**
Model	:	**Ear-hung mask**
Sample Receiving Date	:	**March 23, 2020**
Testing Period	:	**March 23, 2020 ~ March 30, 2020**
Results	:	**Please refer to next page(s).**

****

Summary of Test Results:

	TEST REQUEST	**CONCLUSION**
A	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking	**Pass**

****

Signed for and on behalf of MOSEN

Tested By: Mery — Mery Li

Approved by: Sady — Sady Xu

Mosen Detection Technology Co., Ltd.
Add: No.28-C2010, Xintang Street, Tian'he District, Guangzhou, China
TEL: 4000-220-859 Internet: www.mosen-cert.com

PPE TEST REPORT

Property	Principle / Requirements	Result
Classification	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 and FFP3.	Pass FFP2
Designation	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner: Particle filtering half mask EN 149, year of publication, classification, option (where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask).	Pass
Nominal values and tolerances	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (16 - 32) °C, and the temperature limits shall be subject to an accuracy of±1°C.	Pass +5℃ to+38℃.
Visual inspection	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Pass
Packaging	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use. The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.	Pass
Material	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37°C to allow for the cooling of the air before it reaches the mouth of the dummy head. The air shall be saturated at (37 ± 2)°C at the mouth of the dummy head. In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be inclined so that the water runs away from the mouth and is collected in a trap.	Pass Melt blown filter
Cleaning and disinfecting	If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning	Pass

	and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11.	
Practical performance	Walking test The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min. Work simulation test The individual activities shall be arranged so that sufficient time is left for the comments prescribed.	Pass The particle filtering half mask could undergo practical performance tests under realistic conditions.
Finish of parts	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. Testing shall be done in accordance with 8.2.	Pass. No sharp edges and burrs.
Total inward leakage	1)walking for 2 min without head movement or talking; 2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min; 3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min; 4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min; 5)walking for 2 min without head movement or talking. The leakage P shall be calculated from measurements made over the last 100 s of each of the exercise periods to avoid carry over of results from one exercise to the other.	Pass Total inward leakage is 9%.
Penetration of filter material	The device shall be mounted in a leaktight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment	Pass The penetration of paraffin oil test is 4%. The penetration

	points are exposed to the challenge aerosol. Testing of penetration, exposure and storage shall be done in accordance with EN 13274-7.	of sodium chloride test is 3.3%.
Compatibility with skin	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Pass Inner and out layer: Nonwoven pet fabric
Flammability	The facepiece is put on a metallic dummy head which is motorized such that it describes a horizontal circle with a linear speed, measured at the tip of the nose, of (60 ± 5)mm/s. The head is arranged to pass over a propane burner the position of which can be adjusted. By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the facepiece (when positioned directly over the burner) shall be set to (20 ±2) mm. With the head turned away from the area adjacent to the burner, the propane gas is turned on, the pressure adjusted to between 0,2 bar and 0,3 bar and the gas ignited. By means of a needle valve and fine adjustments to the supply pressure, the flame heigt shall be set to (40 ± 4) mm. This is measured with a suitable gauge. The temperature of the flame measured at a height of (20 ± 2) mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be (800 ± 50)°C. The head is set in motion and the effect of passing the facepiece once through the flame shall be noted. The test shall be repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component shall be passed through the flame once only.	Pass The particle filtering half mask does not to continue to burn for more than 5 s after removal from the flame.
Carbon dioxide content of the inhalation air	For this test the particle filtering half mask shall be fitted securely in a leak-tight manner but without deformation to a Sheffield dummy head (see Figure 6). Air shall be supplied to it from a breathing machine adjusted to 25 cycles/min and 2,0l/stroke and the exhaled air shall have a carbon dioxide content of 5 % by volume. The CO2 is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two	Pass The carbon dioxide content of the inhalation air (dead space) does not exceed an average of 1,0 %

	non-return valves. Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling line and then fed into the exhaled air via a CO2 analyser. To measure the CO2 content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml. Measure the carbon dioxide content of the inhaled air and record continuously.	
Head harness	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Not applicable
Exhalation valve(s)	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10s.	Pass
Breathing resistance	Seal the particle filtering half mask on the Sheffield dummy head. Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continous flow 160 l/min. Use a suitable pressure transducer. Measure the exhalation resistance with the dummy head successively placed in 5 defined positions: facing directly ahead facing vertically upwards facing vertically downwards lying on the left side lying on the right side Test the inhalation resistance at 30 l/min and 95 l/min continuous flow. The breathing resistances apply to valved and	Pass Inhalation resistance at 30 l/min:<0.7mbar. Inhalation resistance at 95 l/min:<2.4mbar. Exhalation resistance at 160 l/min: <3.0mbar.

	valveless particle filtering half masks and shall meet the requirements	
Clogging	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m /h. Fit the sample particle filtering half mask in a leaktight manner to a dummy head or a suitable filter holder located in the dust chamber. Connect the breathing machine and humidifier to the sample and operate for the specified testing time. The concentration of dust in the test chamber may be measured by drawing air at 2 l/min through a sampling probe equipped with a pre-weighed, high efficiency filter (open face,Ndiameter 37 mm) located near the test sample, as shown in Figure 10. Calculate the dust concentration from the weight of dust collected, the flow rate through the filter and the time of collection.	Not applicable
Demountable parts	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Not applicable

NA = Not Applicable

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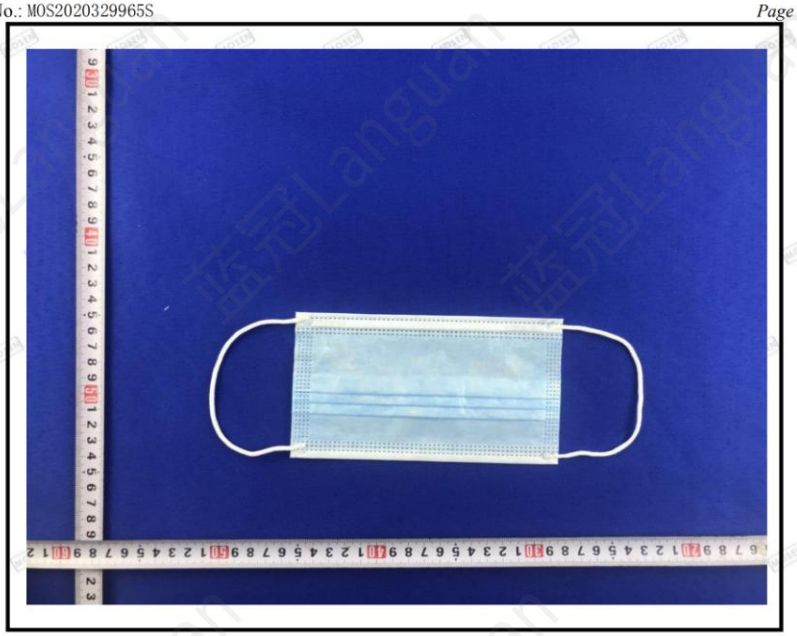
Appendix

Photograph of Sample

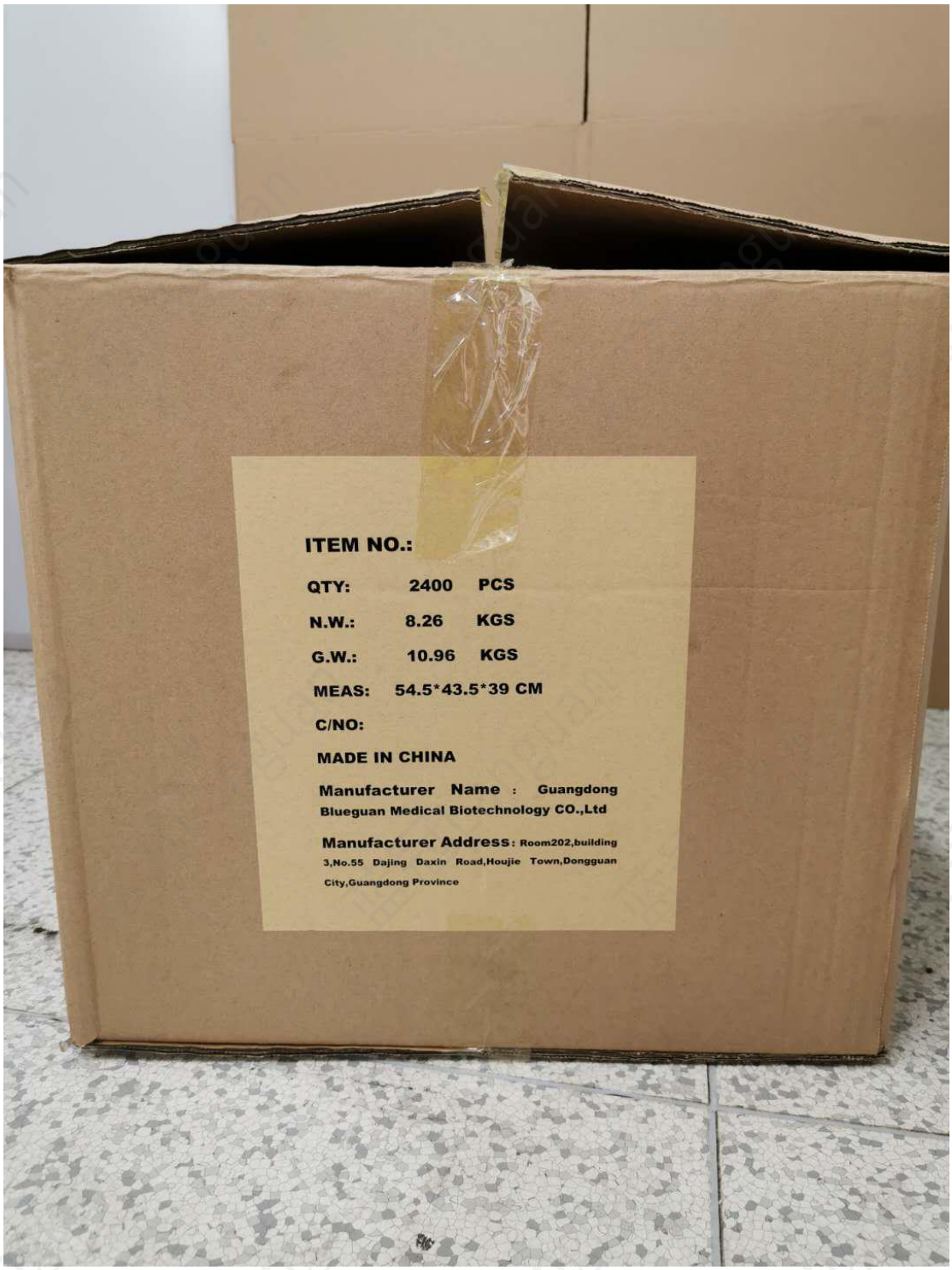
PPE TEST REPORT



MOSEN authenticate the photo on original report only

*** End of Report ***

Mosen Detection Technology Co., Ltd.
Add: No.28-C2010, Xintang Street, Tian'he District, Guangzhou, China
TEL: 4000-220-859 Internet: www.mosen-cert.com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G.W.: 10.96 KGS
MEAS: 54.5*43.5*39 CM
C/NO:
MADE IN CHINA
Manufacturer Name : Guangdong Blueguan Medical Biotechnology CO.,Ltd
Manufacturer Address: Room202,building 3,No.55 Dajing Daxin Road,Houjie Town,Dongguan City,Guangdong Province