9500-N95 MASK

The 9500-N95 masks are extremely durable with a soft and comfortable inner surface, and also have an adjustable nose piece and secured head straps to provide proper fit.

These masks have a 510(K) number for the medical market and can be used TB situations as recommended by OSHA.

NIOSH Approval: TC-84A-5411 FDA 510 (K) : K020474

Why N95 masks?

While single layer nuisance dust masks can help keep you safe during light construction or cleaning activities, they offer little protection against very small particles travelling through the air, like germs from a cough or sneeze, or fine non-poisonous dusts. For protection against small particles, a mask with filtration material, a particulate respirator, is often required.
The most popular of particulate respirators approved by the National Institute for Occupational Safety and Health (NIOSH) is the N95 mask, labeled N95 for their 95% efficiency rating. The N95 masks can filter particles of 0.3 microns.

Because of their low price, effectiveness, and comfort, N95 masks are standard in many industries, and have even become a popular way to prevent the spread of germs among the general public. If you sell to, or are in, the industrial, medical, dental, automotive, tattoo or do-it-yourself markets, many of your customers may require N95 masks. N95 masks must be properly fit tested and are “single use” respirators.

The N95 mask has also become popular in the medical field. NIOSH and the Centers for Disease Control and Prevention (CDC) recommended N95 masks for protection of healthcare workers who come in direct contact with patients with H1N1 and other airborne viruses. There are also N95 masks that are certified by the FDA for use in surgery.

SKU: EW9500-N95

All documentation is on the following pages.

Eastwest Medico Aps
Gotfred Rodes Vej 2
DK-2920 Charlottenlund, Denmark
Phone: +45 7070 1711
Mobile: +45 4027 58881-234-567-8910
Email: info@ewmedico.com

eastwest ew medico

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-17685
Mfr. Reference: MAK-1105

April 19, 2011

Mr. Alexander Freedman, President
Makrite Industries Inc.
236 Upland Avenue
Newton Highlands, Massachusetts 02461-2003

Dear Mr. Freedman:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted March 8, 2011. This request was for an approval of the model 9500-N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAK1105AM1.xls.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. The approval number TC-84A-5411 has been assigned. This respirator is approved for protections against particulates at a N95 filter efficiency level (N95).

The CD enclosed with this letter contains the final respirator label. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely yours,

Heinz W. Ahlers
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Technology Evaluation Branch
Certification, Evaluation and Testing Section
P.O. Box 18070
Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-17685

Manufacturer: Makrite Industries, Inc.

Prepared by: Jeremy Brannen

Tests Conducted by: Jeremy Brannen

Date: March 30, 2011

Respirator Tested: 9500-N95

Background Information

In an application accepted March 8, 2011 Makrite Industries requested an approval of the model 9500-N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAK1105AM1.xls.

Tests Assigned

Test Description	STP Number	Reference
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180
B. Inhalation Resistance Test	TEB-APR-STP-0007	84.180
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059	84.181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See attached test data sheets.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-17685
Test: Exhalation Resistance Test
Manufacturer: Makrite Industries, Inc.

Reference No.: CFR 84.180
STP No.: 3

Filter Type: Filter Only

Item Tested: 9500-N95

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	5.6	PASS
2	25	5.3	PASS
3	25	5.6	PASS

Overall Result: PASS

Comments:

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Jeremy Brammer **Date:** 3/30/2011

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-17685
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: 9500-N95

Reference No.: CFR 84.180
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	6.9	PASS
2	35	6.9	PASS
3	35	6.9	PASS

Overall Result: PASS

Signature: Jeremy Bennett **Date:** 3/30/2011

Engineering Technician

Task Number: TN-17685
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: 9500-N95

Reference No.: CFR 84.180
STP No.: 7

Comments:

Was all equipment verified to be in calibration throughout all testing?	(•) Yes	( ) No

Signature: /Jeremy Brannen/ **Date:** 3/30/2011

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-17685
Test: Sodium Chloride (NaCl) - N95
Manufacturer: Makrite Industries, Inc.
Item Tested: 9500-N95

Reference No.: CFR 84.181
STP No.: 59

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	7.8	5.00	0.373	0.426	PASS
2	85	7.9	5.00	0.375	0.426	PASS
3	85	7.4	5.00	0.777	0.976	PASS
4	85	8.0	5.00	0.568	0.784	PASS
5	85	8.2	5.00	0.605	0.831	PASS
6	85	7.7	5.00	0.684	0.885	PASS
7	85	7.4	5.00	0.724	0.957	PASS
8	85	8.4	5.00	0.346	0.569	PASS
9	85	7.4	5.00	0.281	0.481	PASS
10	85	8.2	5.00	0.293	0.556	PASS
11	85	8.4	5.00	0.543	0.623	PASS
12	85	7.9	5.00	0.643	0.763	PASS
13	85	8.0	5.00	0.738	0.845	PASS
14	85	8.0	5.00	0.516	0.624	PASS
15	85	7.8	5.00	0.548	0.632	PASS
16	85	7.6	5.00	0.726	0.961	PASS
17	85	7.9	5.00	0.536	0.597	PASS
18	85	8.5	5.00	0.555	0.667	PASS
19	85	8.4	5.00	0.842	0.992	PASS
20	85	7.8	5.00	0.743	0.861	PASS

Overall Result: PASS

Signature: Jeremy R Brannen
Engineering Technician

Date: 3/30/2011

Task Number: TN-17685
Test: Sodium Chloride (NaCl) - N95
Manufacturer: Makrite Industries, Inc.
Item Tested: 9500-N95

Reference No.: CFR 84.181
STP No.: 59

Comments:

Was all equipment verified to be in calibration throughout all testing?	(•) Yes	( ) No

Signature: Jeremy Brammer

Date: 3/30/2011

Engineering Technician

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Makrite Industries, Incorporated
C/O Mr. Joseph Zdrok
Joseph Z. Zdrok & Associates
24 Tower Street
Webster, Massachusetts 01570

Re: K020474
Trade/Device Name: Makrite Model 910-N95 Healthcare Particulate Respirator and Surgical Mask
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: May 28, 2002
Received: May 31, 2002

Dear Mr. Zdrok:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Makrite
Life Holds Unlimited Possibilities
知勉工業股份有限公司

MAKRITE INDUSTRIES INC.

11F-5, No.79, Sec.1, Hsin Tai Wu Rd, His-Chih, Taipei Hsien Taiwan, R.O.C. (FAR EAST World Center)

TEL: 886-2-26982419 FAX: 886-2-26982423

Date: May, 6, 2011

Subject: Risk Analysis for Makrite's 9500-N95 Mask

To: **Letter to the 510(k) File**

From: Bob Wen, Vice Chairman, Makrite Industries, Inc.

MAKRITE MODEL 9500-N95 RESPIRATOR AND SURGICAL MASK

The Model 9500-N95 has been designed as the ultrasonically head strap welded version of the MAKRITE TYPE N95 RESPIRATOR AND SURGICAL MASK MODEL 910-N95. The 910-N95 cone shaped medical mask is the subject of K020474. This letter to file documents the process whereby Makrite has determined that the new model, 9500-N95, is covered by the original Premarket Notification, K020474, and does not require a separate, new 510(k) application.

The materials in both masks are identical, as shown in the product specifications. The Model 9500-N95 meets the same performance specifications as the original 910-N95 mask.

The FDA guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device" was used to reach the determination that the change may be documented to file. Specifically, Flow Chart B in the guidance differentiates between changes in specifications that require a new 510(k) and those that do not. A copy of Flow Chart B, marked to show the decision path, is attached to this letter to file.

Makrite followed the procedures under the Design Changes portion of its Quality System to determine required verification and validation for the change. The new model meets the Design Control requirements in Makrite's Quality System. As noted, Design Validation testing demonstrates the new model meets the same performance specifications as the original and does not raise any new questions of safety or effectiveness.

Attachments:

1. Flowchart B from the 510(k) change guidance.

Bob Wen, Vice Chairman, Makrite Industries, Inc.

风险监测检验报告

No:20J000382

防伪码：GILB-0935-24

产品名称	随弃式口罩	商标	MAKRITE	规格型号	9500-N95/---
生产日期/批号	2020-02-01/---				
受检单位名称和地址	东莞迅安塑胶纤维制品有限公司 地址：东莞市塘厦镇诸佛岭工业区				
生产单位名称和地址	东莞迅安塑胶纤维制品有限公司 地址：东莞市塘厦镇诸佛岭工业区				
任务来源	东莞市市场监督管理局				
采样日期	2020-02-01	采样人员	张凯莹 田国梁 萧活立	样品到达日期	2020-02-02
采样数量	18个检验/10个备样	采样地点	成品末端	检查封样人员	潘红琴
样品等级	合格品	采样单编号	DG0120020101	封样状态	完好
检验依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》 GB 15979-2002 《一次性使用卫生用品卫生标准》				
检验结论	所检项目符合GB 2626-2006、GB 15979-2002标准要求。 广州检验检测认证集团有限公司 检验检测专用章 (GF2) 签发日期：2020-02-10				
备注	本报告检验地址为广州市番禺区石楼潮田工业区珠江路1-2号。				

批准：冯文　　审核：方明　　主检：曹李娜

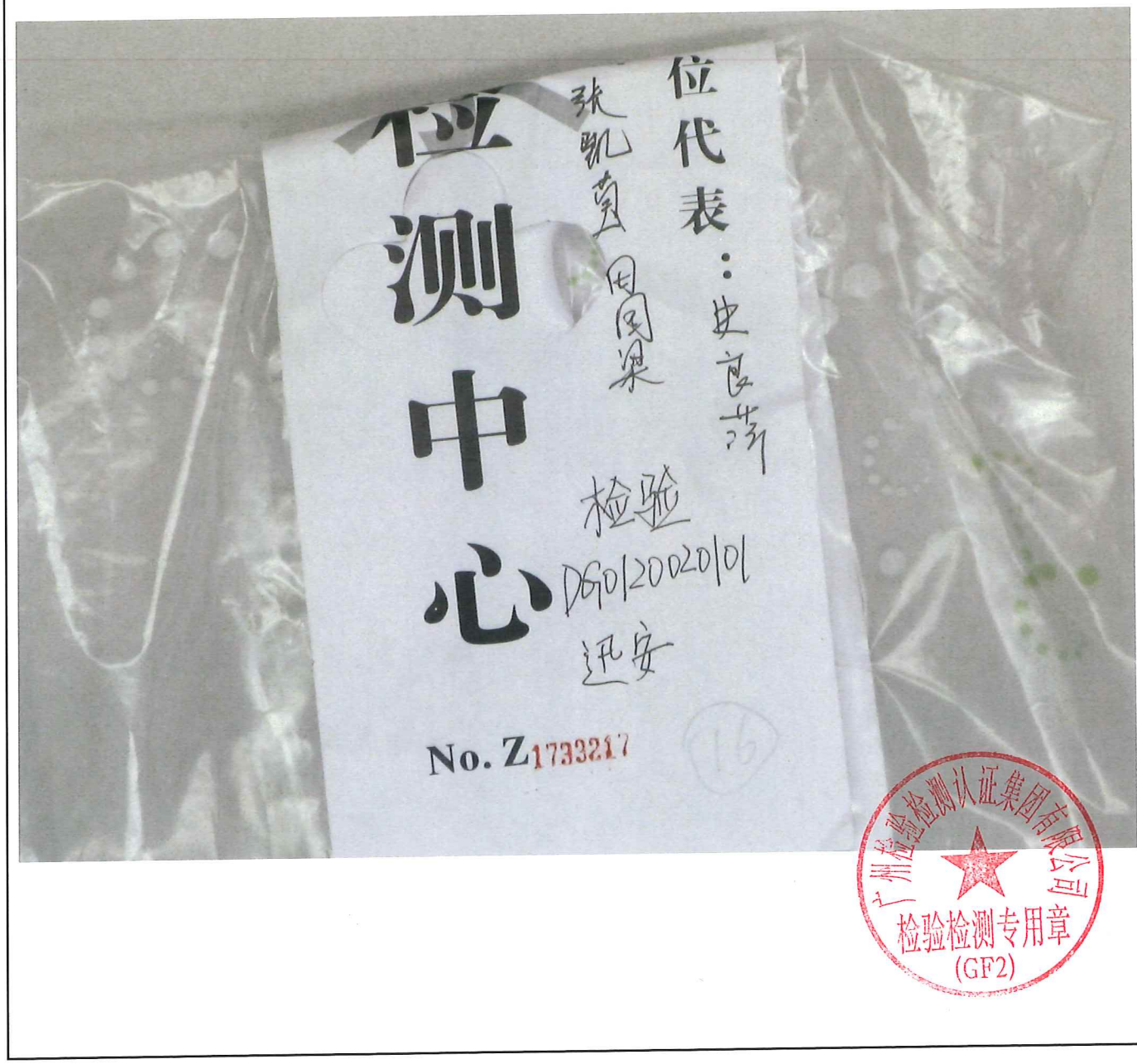
风险监测检验报告

No:20J000382

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

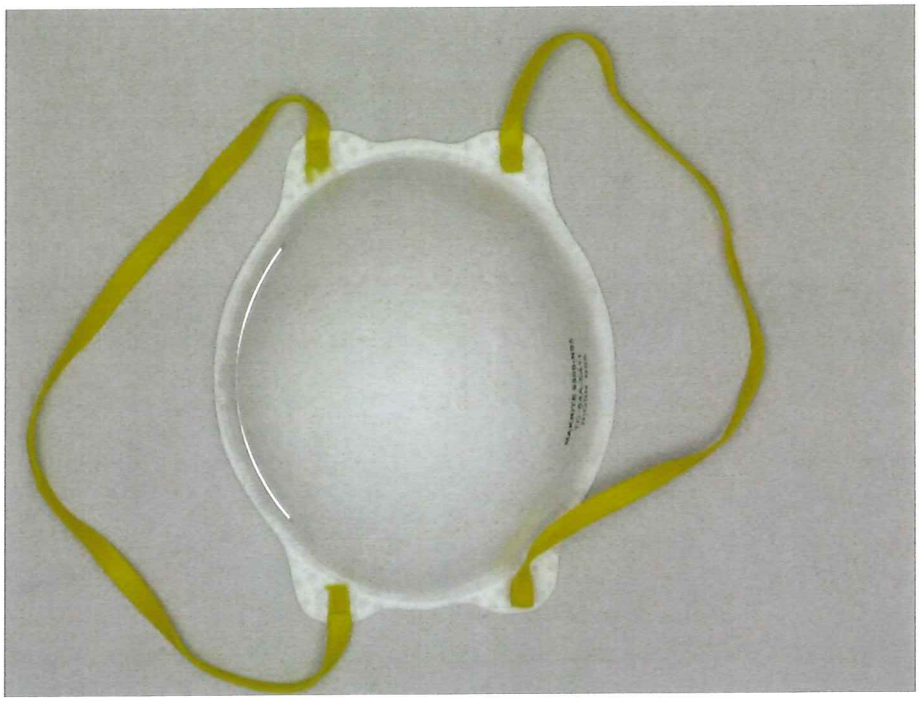
风险监测检验报告

No:20J000382



风险监测检验报告

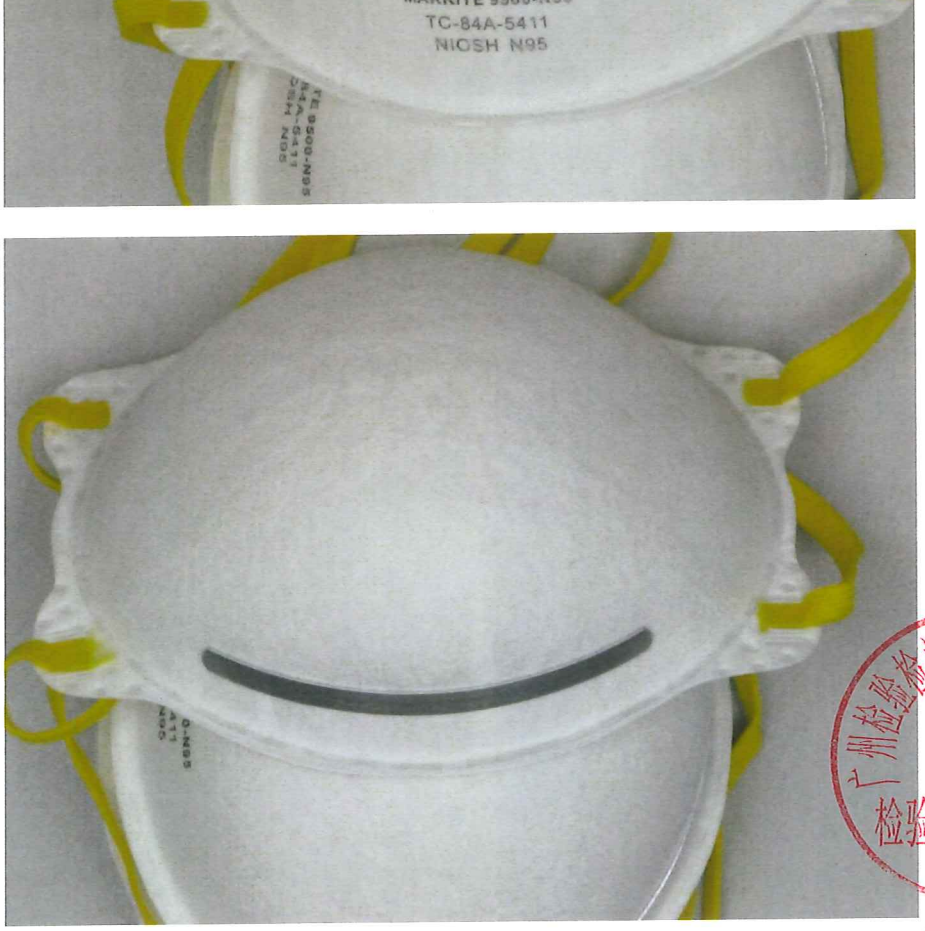
No:20J000382



广州检验检测认证集团有限公司 检验检测专用章 (GF2)

风险监测检验报告

No:20J000382



风险监测检验报告

No:20J000382

检验检测项目(计量单位)[样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●NaCl颗粒物过滤效率	GB 2626-2006 6.3 空气流量:85L/min 气溶胶颗粒:NaCl 气溶胶浓度:15mg/m³ 温度:23.0℃ 相对湿度:35.8%	过滤效率(%): ≥95.0 (KN95)	过滤效率(%): 未处理样品 1# 99.375 2# 99.584 3# 99.425 4# 99.657 5# 99.389 6# 99.175 7# 99.257 8# 99.316 9# 99.578 10# 99.621 温湿度预处理后样品 1# 98.83 2# 98.80 3# 99.177 4# 99.175 5# 98.89	符合	
●吸气阻力(Pa)	GB 2626-2006 6.5	≤350	未处理样品 1# 34.7 2# 35.2 温湿度预处理后样品 1# 31.0 2# 47.2	符合	
●呼气阻力(Pa)	GB 2626-2006 6.6	≤250	未处理样品 1# 36.1 2# 35.9 温湿度预处理后样品 1# 37.8 2# 34.8	符合	
●致病性化脓菌	GB 15979-2002 附录B	不得检出	绿脓杆菌 未检出 金黄色葡萄球菌 未检出 溶血性链球菌 未检出	符合	
●大肠菌群	GB 15979-2002 附录B	不得检出	未检出	符合	
●细菌菌落总数(CFU/g)	GB 15979-2002 附录B	≤200	40	符合	
●真菌菌落总数(CFU/g)	GB 15979-2002 附录B	≤100	20	符合	
备注	(本栏空白)				

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

——本报告结束——