Disposable face mask

KGT®
Instruments & Equipments

Composition	Disposable face mask is made of non woven fabric, breathable and soft, with excellent filtration; odorless, skin-friendly, latex and fiberglass free. Bacterial filtration: BFE 95% - 99% With flexible nose clipon
Size	17.5x9.5cm, 16.5x9.5cm, 17.5x9cm, 18x9cm; for adult and children use.
Specification	Top Layer-20 GSM Middle Layer-18 GSM Bottom Layer-20 GSM
Type	2 earloops, 4 ties, with a face shield.
Layer	2-ply, 3-ply, 4-ply, 6-ply, etc.
Color	white, green, blue, pink, yellow, etc.
Packing	5 to 10 pcs/pack, 50 pcs/box

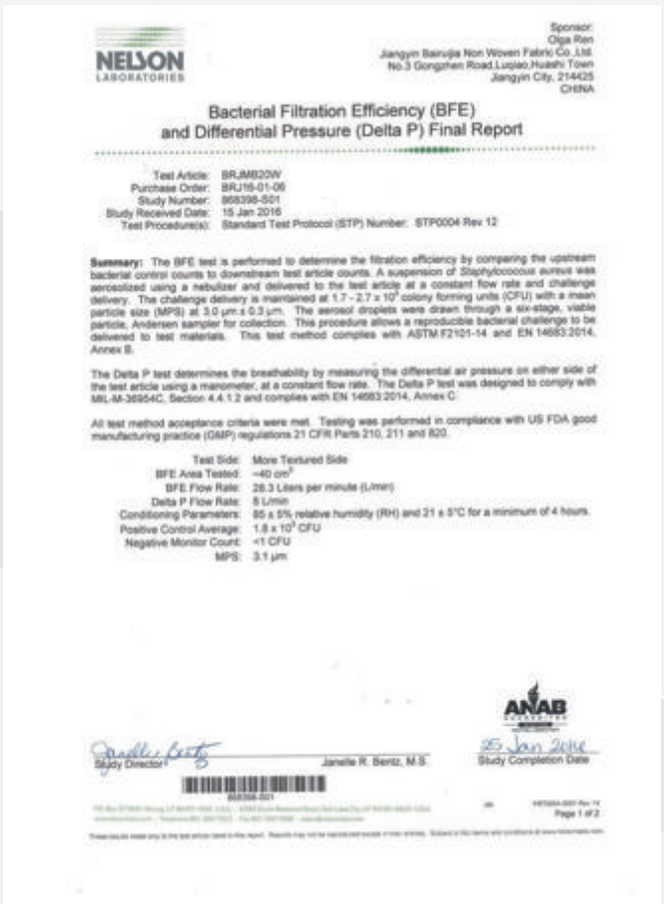
Beijing Kanggaote Instruments and Equipments Co.Ltd

Email:info@kanggaote.com
Whatsapp:0086-13810851425

Disposable face mask

KGT®
Instruments & Equipments

Quality Assurance: Testing Report and CE Certificate



NELSON LABORATORIES

Sponsor:
Olga Ren
Jiangyin Bairuijia Non Woven Fabric Co.,Ltd.
No.3 Gongzhen Road,Luqiao,Huashi Town
Jiangyin City, 214425
CHINA

Bacterial Filtration Efficiency (BFE)
and Differential Pressure (Delta P) Final Report

Test Article: BRJMB20W
Purchase Order: BRJ16-01-06
Study Number: 868398-S01
Study Received Date: 15 Jan 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 12

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM-F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: More Textured Side
BFE Area Tested: ~40 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.
Positive Control Average: 1.8 x 10^3 CFU
Negative Monitor Count: <1 CFU
MPS: 3.1 µm

ANAB

Janelle R. Bentz, M.S.
Study Director

25 Jan 2016
Study Completion Date

868398-S01

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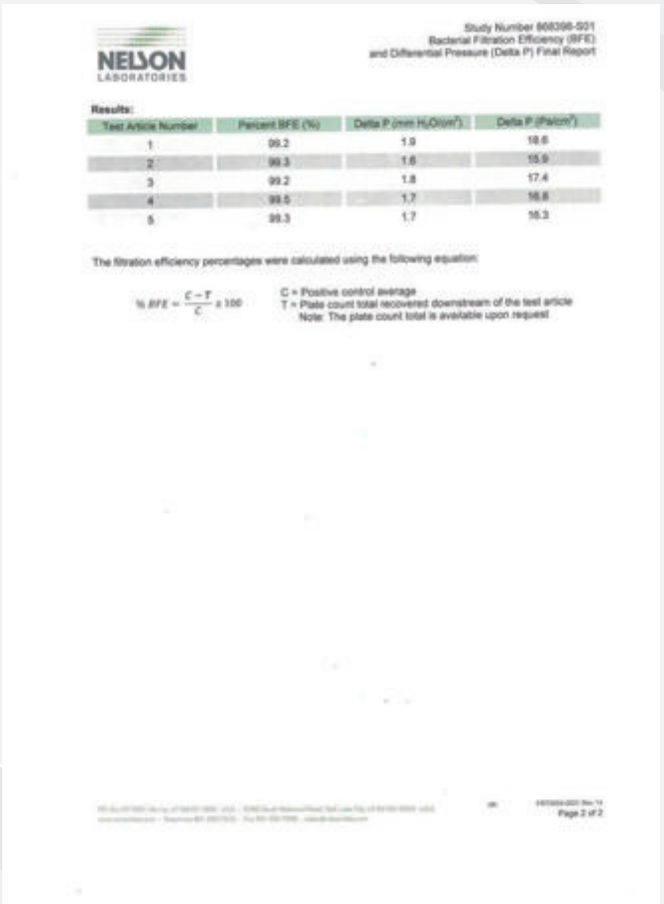

NELSON LABORATORIES

Study Number 868398-S01
Bacterial Filtration Efficiency (BFE)
and Differential Pressure (Delta P) Final Report

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.2	1.9	18.6
2	99.3	1.6	15.9
3	99.2	1.8	17.4
4	99.5	1.7	16.8
5	99.3	1.7	16.3

The filtration efficiency percentages were calculated using the following equation:

$$\%\,BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Disposable face mask

KGT®
Instruments & Equipments

CERTIFICATE

No. Q6 17 10 48400 014

Holder of Certificate: Wujiang Kangjie Medical Material Co., Ltd.
Zhenze Town
Wujiang District
215231 Suzhou City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Wujiang Kangjie Medical Material Co., Ltd. Zhenze Town, Wujiang District, 215231 Suzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Production and Distribution of Sterile Wound Dressings, Sterile Medical Kits, Sterile Bandages, Sterile Face Mask, Sterile Cotton Dressings

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1720204
Valid from: 2018-01-02
Valid until: 2021-01-01

Date, 2017-12-29

Stefan Preiß

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS

认证证书

证书号: Q6 17 10 48400 014

证书持有者： 吴江康洁医用材料有限公司
中华人民共和国江苏省苏州市吴江区震泽镇 215231

生产场地： 吴江康洁医用材料有限公司
中华人民共和国江苏省苏州市吴江区震泽镇 215231

认证标志：

认证范围： 生产和分销：
无菌伤口敷料、无菌医用组合包
无菌绷带、无菌口罩
无菌棉制敷料

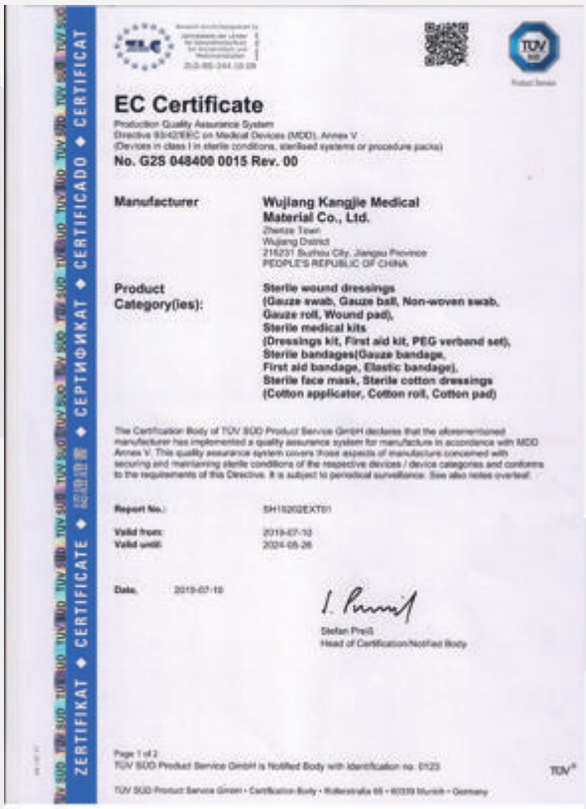
认证标准： EN ISO 13485:2016
医疗器械 - 质量管理体系 - 用于法规的要求
(ISO 13485:2016)
DIN EN ISO 13485:2016

证书号： SH1720204
生效期： 2018-01-02
有效期： 2021-01-01
发证日期： 2017-12-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 048400 0015 Rev. 00

Manufacturer: Wujiang Kangjie Medical Material Co., Ltd.
Zhenze Town
Wujiang District
215231 Suzhou City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Sterile wound dressings
(Gauze swab, Gauze ball, Non-woven swab, Gauze roll, Wound pad),
Sterile medical kits
(Dressings kit, First aid kit, PEG verband set),
Sterile bandages(Gauze bandage, First aid bandage, Elastic bandage),
Sterile face mask, Sterile cotton dressings
(Cotton applicator, Cotton roll, Cotton pad)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1920GEXT01
Valid from: 2019-07-10
Valid until: 2024-05-26

Date, 2019-07-10

Stefan Preiß
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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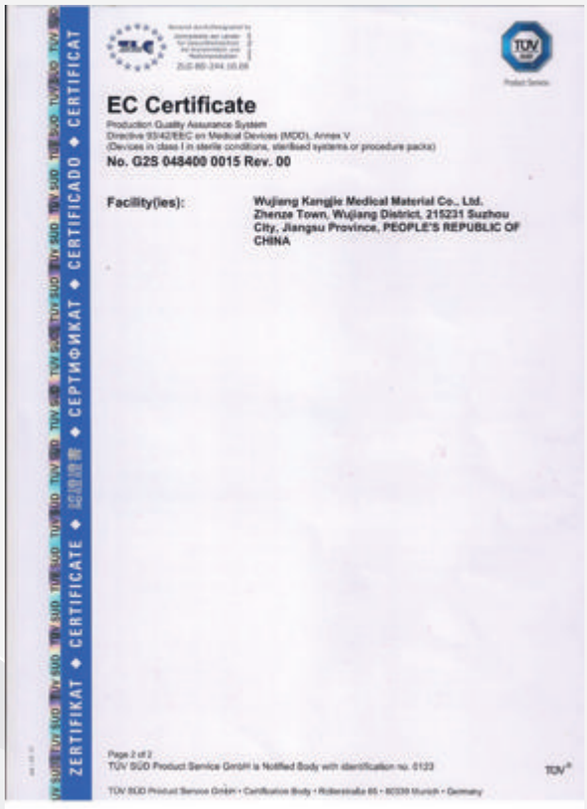

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