MKW Surgical Mask – EN 14683 Typ IIR – CE-Zertifiziert - Art. Nr. 28818

Eigenschaften

- 3-lagig
- mit hochelastischen Ohrschlaufen
- Hypoallergen, glasfaser- und latexfrei
- mit eingearbeitetem, formbarem Nasenbügel (flexibler Draht, ummantelt mit Kunststoff)
- Farbe blau
- 50er Box
- Verpackungsbox ist 4-sprachig (Deutsch/Französisch/Italienisch/Englisch)
- EAN Code 6970101550008

Qualitätsstandard

- Entspricht dem europäischen Standard EN 14683:2019 Typ IIR
- CE-Zertifiziert
- Medizinprodukt Klasse I
- Swissmedic gemeldet
- Filtrationsleistung: ≥ 98%

Abmessung des medizinischen Mundschutzes

- Länge: 175mm ± 2mm
- Breite: 95mm ± 2mm

Verpackung

- 50 Masken pro Box
- 40 Boxen pro Karton (=2000 Masken pro Karton)
- 20 Karton's pro Palette (=800 Boxen pro Palette / 40'000 Masken pro Palette)

Karton

- Masse: 50 x 41 x 30.5cm
- Gewicht: 9kg

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 044172 0028 Rev. 01

Holder of Certificate: **Jiangsu Feixia Medical Products Co., Ltd**
No. 89 Bin He Road, Jiang Duo Town
Jiangyan District
225503 Taizhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Jiangsu Feixia Medical Products Co., Ltd
No. 89 Bin He Road, Jiang Duo Town, Jiangyan District, 225503
Taizhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Sterile Gauze Sponges, Sponges with X-ray Detectable Thread, Cotton Ball, Gauze Bandages, Lap Sponge with X-ray Detectable Thread, Lap Sponge without X-ray Detectable Thread, Gauze Ball, Cutting Gauze, First-dressing Bandage, Elastic Bandage, Absorbent Gauze, Non-woven Wound Care Products, Gauze Roll, Cotton Tip Applicator, Dental Cotton Roll, Surgical Mask, Non-woven Sponge, Dry Wipe, Sterile Gauze Swabs, Sterile Lap Sponge, Sterile First-Dressing Bandage, Medicine Cup for Single Use**

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.: SH1912701

Valid from: 2020-02-01
Valid until: 2023-01-31

Date, 2020-01-08

Christoph Dicks
Head of Certification/Notified Body

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

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

A4 / 07.17

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 044172 0026 Rev. 01

Manufacturer:

Jiangsu Feixia Medical Products Co., Ltd
No. 89 Bin He Road, Jiang Duo Town
Jiangyan District
225503 Taizhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Jiangsu Feixia Medical Products Co., Ltd
No. 89 Bin He Road, Jiang Duo Town, Jiangyan District, 225503
Taizhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Lap Sponges with X-ray Detectable Thread,
Gauze Ball with X-ray Detectable Thread,
Gauze Sponge with X-ray Detectable Thread

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19127CN01

Valid from: 2019-10-28
Valid until: 2022-06-13

Date, 2019-10-28

Stefan Preiß
Head of Certification/Notified Body

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

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 044172 0027 Rev. 01

Manufacturer

Jiangsu Feixia Medical Products Co., Ltd
No. 89 Bin He Road, Jiang Duo Town
Jiangyan District
225503 Taizhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Jiangsu Feixia Medical Products Co., Ltd
No. 89 Bin He Road, Jiang Duo Town, Jiangyan District, 225503
Taizhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Gauze Sponges without X-ray Detectable Thread,
Lap Sponge without X-ray Detectable Thread,Gauze Bandage, Fast Dressing Bandage,
Gauze Ball without X-ray Detectable Thread,
Cutting Gauze, Gauze Roll, Elastic Bandage,
Cotton Tip Applicator, Surgical Mask, Cotton Ball,
Dental Cotton Roll, Non-woven Sponge, Dry Wipe,
Sterile Gauze Swabs, Sterile Lap Sponge,
Sterile First-Dressing Bandage,
Medicine Cup for Single Use**

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.: SH19127CN01

Valid from: 2019-10-28
Valid until: 2022-06-13

Date, 2019-10-28

Stefan Preiß
Head of Certification/Notified Body

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

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Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

认 证 证 书

证书号. Q6 044172 0028 Rev. 01

证书持有者： **江苏省飞霞医保用品有限公司**
中华人民共和国江苏省泰州姜堰区蒋垛镇滨河路89号 225503

生产场地： 江苏省飞霞医保用品有限公司
中华人民共和国江苏省泰州姜堰区蒋垛镇滨河路89号 225503

认证标志：

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

认证范围： **生产和分销：**
消毒纱布巾，带X线纱布巾，棉球，纱布绷带，带X线腹部巾，不带X线腹部巾，纱布球，纱布切片，急救绷带，弹性绷带，脱脂纱布，无纺布辅料产品，纱布卷，棉签，牙科棉，手术口罩，无纺布巾，干巾，消毒纱布片，消毒腹部巾，消毒急救绷带，一次性医用药杯

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

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系（删除第7.3条款）。

报告号： SH1912701

生效期： 2020-02-01

有效期： 2023-01-31

发证日期， 2020-01-08

Christoph Dicks
Head of Certification/Notified Body

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

本证书是由具有法律效力的英文证书翻译而来

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EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	**JIANGSU FEIXIA MEDICAL PRODUCTS CO., LTD** **No.89 Bin He RD, Jiang Duo Town** **Jiangyan District** **225503 Taizhou, Jiangsu Province** **China**
European Authorized Representative:	**SUNGO EUROPE B.V.** **Olympisch Stadion 24** **1076DE** **Amsterdam** **Netherlands**

We declare under our sole responsibility that

the medical device	**Masks, surgical**
UMDNS Code	**12458**
of class	**I**

meets the provision of the directive 93/42/EEC and its transposition in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

JIANGSU FEIXIA MEDICAL PRODUCTS CO., LTD. 江苏省飞霞医保用品有限公司

TAIZHOU, 2020/06/29

Place, Date

Signature of Representative

Test Report

Applicant: [redacted]

Address: [redacted]

The following sample(s) was/were submitted and identified on behalf of the client as:

Product name:	SURGICAL MASK
Model:	Earloop
batch number:	AMA20-01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16/17/18/19/20
Trade mark:	MKW
Classification:	Type IIR
Sample quantity:	105 Pcs
Sample Received Date:	Sep. 23, 2020
Testing Period:	Sep. 23, 2020~ Oct. 12, 2020

Test Requirement:

According to the requirement of the client, the test item of the sample is according to the standard EN 14683:2019+AC:2019.

Test Result(s): Please refer to the following page(s)

Test Method: Please refer to the following page(s)

Compiled by: _____ Reviewed by: _____

Approved by: _____ Date: 2020-10-12

Shenzhen NTEK Testing Technology Co., Ltd. Report Seal

Test Result(s):

Tests performed	Test Standards	Test Requirements	Test results		Conclusion
1. Bacterial filtration efficiency (BFE)*	EN 14683-2019 Clause 5.2.2	Bacterial filtration efficiency: The BFE shall conform to the minimum value given for the relevant type when tested in accordance Annex B: Type I: ≥95%, Type II & IIR: ≥98%	1#	99.86%	Pass
			2#	99.81%	
			3#	99.77%	
			4#	99.77%	
			5#	99.81%	
2. Breathability	EN 14683-2019 Clause 5.2.3	Breathability: The differential pressure shall conform to the value when tested in accordance with Annex C: Type I & II: < 40Pa/cm^2 Type IIR: < 60Pa/cm^2	Detail refer to Appendix 1		Pass
3. Splash resistance	EN 14683-2019 Clause 5.2.4	Splash resistance: The splash resistance shall conform to the minimum value for type IIR when tested in accordance with ISO 22609:2004: ⩾ 16.0 kPa	The specimens have been tested without penetration by Synthetic Blood		Pass

Tests performed	Test Standards	Test Requirements	Test results	Conclusion
4.Microbial cleanliness (Bioburden)	EN 14683-2019 Clause 5.2.5	Bioburden: The bioburden shall be≤30CFU/g tested when tested according to EN ISO 11737-1:2018	Detail refer to Appendix 2	Pass

Appendix 1: Summarization of Test Data

TABLE: Breathability-differential pressure							Pass
Sample No.	Top left	Top right	Centre	Down left	Down right	Average	--
6#	22.5	21.6	21.5	21.5	21.6	21.7	Pass
7#	23.2	17.1	21.9	22.2	22.4	21.4	Pass
8#	20.0	22.6	22.3	24.9	23.8	22.7	Pass
9#	21.3	22.8	23.0	21.3	23.6	22.4	Pass
10#	23.0	20.6	19.7	21.5	20.5	21.1	Pass
Note: unit: Pa/cm^2. Limit of type I & II: < $40Pa/cm^2$ Limit of type IIR: < $60Pa/cm^2$							

Appendix 2: Summarization of Test Data

Sample No.	11#	12#	13#	14#	15#
Bioburden/ mask (CFU)	60	30	39	30	48
Bioburden/gram (CFU/g)	19.3	9.7	12.6	9.4	15.2
Note: Limit of type I & II& IIR:≤30CFU/g					

Remark:

*Each test specimen has been conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for 4 h.

Sample photo(s):

Fig.1

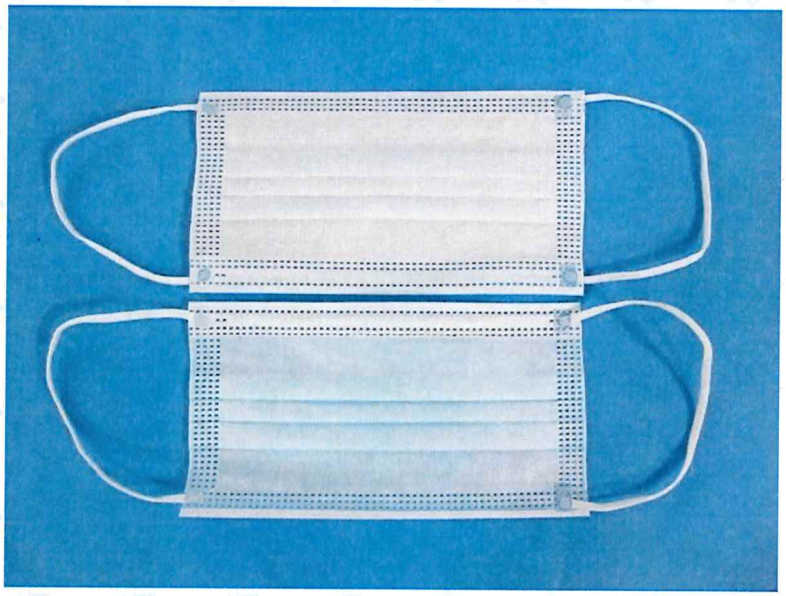

Fig.2

****End of Report****

The test report is effective only with both signature and specialized stamp, the result(s) shown in this report refer only to the sample(s) tested. Without written approval of NTEK, this report can't be reproduced except in full; The laboratory is not responsible for the authenticity of the sample information provided by the customer; The laboratory is not responsible for any deviation of results due to methods/standards provided by the customer.

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Test Report

Number: GZHT02331902

Report Ref:	GZHT02331902		
Date Received:	Aug 27, 2020	**Date Issued:**	Sep 02, 2020

Company Name: **Address:**	ACUMAX MED AG PROMENADENSTRASSE 6 5330 BAD ZURZACH SWITZERLAND
Contact Name:	Manuel Welti

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses	:	Medical Face Mask
Ratings	:	Type IIR
Sample Name	:	Disposable Protection Masks OEM Brand MKW
No. Of Sample	:	One(100 pieces)
Size	:	17.5*9.5cm
Colour	:	Light Blue
Standard	:	EN 14683:2019+AC:2019
Brand Name	:	MKW
Date received/ Test Started	:	Aug 27, 2020
Ref	:	AMA-20-01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16/17/18/19/20

Test was conducted on specific items, at our client's request.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin
General Manager

WEN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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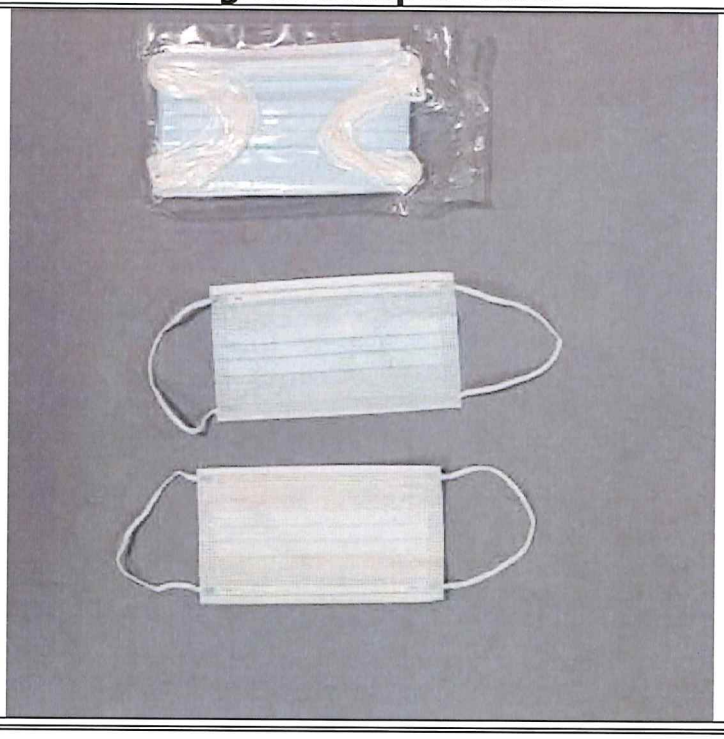
Test Report

Number: GZHT02331902

Original Sample Photo



Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin
General Manager

WEN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

Test Report

Number: GZHT02331902

Summary of testing:
With reference to following standard: • EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type IIR
Materials Used in The Submitted Sample Were Found To Comply With The Type IIR Requirements of EN 14683:2019+AC:2019 with respect to Bacterial Filtration Efficiency, Differential Pressure and Splash Resistance Pressure tests.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin
General Manager

WEN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

Test Report

Number: GZHT02331902

Tests Conducted (As Requested By The Applicant)

1 Differential Pressure (EN 14683:2019+AC:2019 Annex C):
Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm^2.

Tested Sample	Result (Pa/cm^2)*					Performance Requirement for Medical Face Mask (Pa/cm^2)
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	56.3	64.8	62.5	61.6	57.4	Type IIR: <60
Location 2	56.8	55.4	50.0	52.6	50.0	
Location 3	52.9	60.9	60.3	55.4	45.3	
Location 4	58.0	53.9	54.0	49.2	62.3	
Location 5	52.8	54.5	50.1	54.5	53.8	
Average	55.4	57.9	55.4	54.7	53.8	
* = All the locations were evenly taken from the main mask body.						

2 Splash Resistance Pressure (*ISO 22609:2004*):
Synthetic Blood Surface Tension: 0.042 N/m, Distance Between Blow Head Front End And Target Area: 305 mm, Artificial Blood Volumes: 2 mL, Blood Pressure: 16.0 kPa, Velocity: 550 cm/s, Without Targeting-plate Used
Condition test specimens for a minimum of 4 hours in an environment of temperature (21±5) °C and relative humidity (85±5)% and conduct the test within 1 minute of removal from conditioning chamber.

Tested Sample	Observation	Pass/Fail	Performance Requirement for Medical Face Mask
			Type IIR:
Specimen (1)	No penetration	Pass	No Penetration at 16.0 kPa
Specimen (2)	No penetration	Pass	
Specimen (3)	No penetration	Pass	
Specimen (4)	No penetration	Pass	
Specimen (5)	No penetration	Pass	
Specimen (6)	No penetration	Pass	
Specimen (7)	No penetration	Pass	
Specimen (8)	No penetration	Pass	
Specimen (9)	No penetration	Pass	
Specimen (10)	No penetration	Pass	
Specimen (11)	No penetration	Pass	
Specimen (12)	No penetration	Pass	
Specimen (13)	No penetration	Pass	
Specimen (14)	No penetration	Pass	
Specimen (15)	No penetration	Pass	

WEN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

Test Report

Number: GZHT02331902

Tests Conducted (As Requested By The Applicant)

Specimen (16)	No penetration	Pass
Specimen (17)	No penetration	Pass
Specimen (18)	No penetration	Pass
Specimen (19)	No penetration	Pass
Specimen (20)	No penetration	Pass
Specimen (21)	No penetration	Pass
Specimen (22)	No penetration	Pass
Specimen (23)	No penetration	Pass
Specimen (24)	No penetration	Pass
Specimen (25)	No penetration	Pass
Specimen (26)	No penetration	Pass
Specimen (27)	No penetration	Pass
Specimen (28)	No penetration	Pass
Specimen (29)	No penetration	Pass
Specimen (30)	No penetration	Pass
Specimen (31)	No penetration	Pass
Specimen (32)	No penetration	Pass
Conclusion*:	**Accepted**	

* = An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

WEN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

Test Report

Number: GZHT02331902

Tests Conducted (As Requested By The Applicant)

3 Bacterial Filtration Efficiency (BFE)

As Per EN 14683:2019+AC:2019 Medical face masks – Requirements And Test Methods Annex B.

Test Item	Results (%)					Performance Requirement for Medical Face Mask (%)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	99.9	>99.9	>99.9	>99.9	>99.9	Type IIR: ≥98

Remarks:

1. Biological Aerosol: *Staphylococcus aureus* (ATCC 6538).
2. Testing side: Inside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78 cm^2
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2.0×10^3 CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit

Remark: This test item was conducted in Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

End of Report

WEN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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BFE ≥98%
EN14683:2019(Type IIR)
OPEN
3-ply 50pcs
INTRODUCTION FOR USE / BEDIENUNGSANLEITUNG / MODE D'EMPLOI / ISTRUZIONI PER I'USO
MD
Attention
1. Please check before using if the package is in good condition and ensure that use is before expiry date.
2. Recommanded using time is within 24 hours.
3. Check use if you are allergic to nonwoven materials.
4. Use according to requirements of hospitals or Office of Public Health.
5. Transportation rules: prevent package from heavy pressing, direct sunlight and exposure to rain or snow.
DISPOSABLE / EINWEG / USAGE UNIQUE / USA E GETTA
LATEX FREE / LATEXFREI / SANS LATEX / SENZA LATEX
SURGICAL MASK
CHIRURGISCHE MASKE
MASQUE CHIRURGICAL
MASCHERINA CHIRURGICA
BFE ≥98%
EN14683:2019(Type IIR)
3-ply 50pcs
Art.Nr: 28818
Lot No: AMA-20-01
Mfg.Date: 2020-09
Exp.Date: 2022-08
Standard Used: EN14683:2019(Type IIR)
Shelf-life: 2 years
JIANGSU FEIXIA MEDICAL PRODUCTS CO, LTD.
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AcuMax Med AG
5330 Bad Zurzach
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MADE IN CHINA