Medizinische Maske Typ II R, **Anti-Fog, zum Binden**

Masque Médicale Typ II R, **Anti- buée, à relier**

Maschere médica Typo II R, **Anti- nebbia, a nastro**

Medical Face Mask Type II R, **Anti-Fog, tie-on**

Characteristics	Verpackung
Medizinische Maske Typ II R **Anti-Fog, zum Binden** Spezifikation: ▪ 3- Schichtenmaske EN14683 ▪ CE zertifiziert ▪ Bakterielle Filterleistung ≥ 98 % ▪ Druck des Spritzwiderstands ≥ 120 ▪ Unsteril ▪ **Antifog- Wirkung durch Schaumstoff, der entlang des Nasenbügels platziert ist.** Dimensionen: ▪ Maske: 17.5 x 9.5 cm ▪ Bändel: 2 x 90 cm ▪ 1 Bändel: 40.5 cm 	Box: ▪ Masken pro Box: 50 Stk. ▪ Dimensionen: 190 x 100 x 130 mm ▪ Gewicht: tbd Karton: ▪ Boxen pro Karton: 40 Boxen ▪ Dimensionen: 40 x 52 x 50 cm ▪ Gewicht: 10 kg

Medizinische Maske Typ II R, **Anti-Fog, zum Binden**

Masque Médicale Typ II R, **Anti- buée, à relier**

Maschere médica Typo II R, **Anti- nebbia, a nastro**

Medical Face Mask Type II R, **Anti-Fog, tie-on**

Characteristics	Emballage
Masque Médicale Typ II R **Anti- buée, à relier** Spécification: ▪ Masque à 3 couches EN14683 ▪ Certifié CE ▪ Efficacité de la filtration bactérienne ≥ 98 ▪ Pression de la résistance aux éclaboussures ≥ 120 ▪ Unsteril ▪ **Effet antibuée grâce à une mousse le long du nez.** Dimensions: ▪ Masque: 17.5 x 9.5 cm ▪ Ruban: 2 x 90 cm ▪ 1 Ruban: 40.5 cm 	Boîte: ▪ Masques par boîte: 50 pcs. ▪ Dimensions: 190 x 100 x 130 mm ▪ Poids: tbd Carton: ▪ Boîtes par carton: 40 boîtes ▪ Dimensionen: 40 x 52 x 50 cm ▪ Poids: 10 kg

Stöckli Medical AG · Länggasse 4 · CH-6208 Oberkirch · Phone Direct: 079 214 42 45 · Phone: 041 925 66 55 · www.stoecklimedical.ch

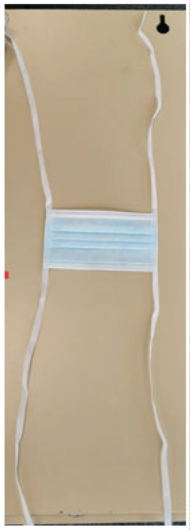
Medizinische Maske Typ II R, **Anti-Fog, zum Binden**

Masque Médicale Typ II R, **Anti- buée, à relier**

Maschere médica Typo II R, **Anti- nebbia, a nastro**

Medical Face Mask Type II R, **Anti-Fog, tie-on**

Characteristics	Imballaggio
Maschere médica Typo II R **Anti- nebbia, a nastro** Specifica: ▪ Maschera a 3 strati EN14683 ▪ Certificato CE ▪ Efficienza di filtrazione batterica ≥ 98 %. ▪ Pressione della resistenza agli spruzzi ≥ 120 ▪ Unsterile ▪ **Effetto antiappannamento grazie alla schiuma posta lungo il nasello.** Dimensioni: ▪ Maschera: 17.5 x 9.5 cm ▪ Nastro: 2 x 90 cm ▪ 1 Nastro: 40.5 cm	Scatole: ▪ Maschere per scatole: 50 pzo. ▪ Dimensionen: 190 x 100 x 130 mm ▪ Peso: tbd Cartone: ▪ Scatole per cartone: 40 scatole ▪ Dimensioni: 40 x 52 x 50 cm ▪ Peso: 10 kg

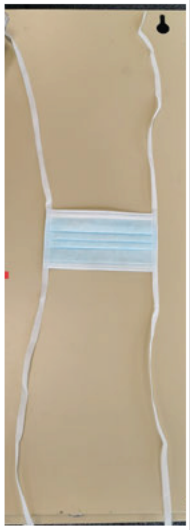


Medizinische Maske Typ II R, **Anti-Fog, zum Binden**

Masque Médicale Typ II R, **Anti- buée, à relier**

Maschere médica Typo II R, **Anti- nebbia, a nastro**

Medical Face Mask Type II R, **Anti-Fog, tie-on**

Characteristics	Verpackung
Medical Face Mask Type II R **Anti-Fog, tie-on** Specification: ▪ 3 layer mask EN14683 ▪ CE certified ▪ Bacterial filtration efficiency ≥ 98 % ▪ Splash resistor pressure ≥ 120 ▪ Non-sterile ▪ **Antifog effect due to a foam placed along the nose bar.** Dimensions: ▪ Masks: 17.5 x 9.5 cm ▪ Ribbon: 2 x 90 cm ▪ 1 ribbon: 40.5 cm 	Box: ▪ Masks per box: 50 pcs. ▪ Dimensions: 190 x 100 x 130 mm ▪ Weight: tbd Carton: ▪ Boxes per carton: 40 Boxes ▪ Dimensions: 40 x 52 x 50 cm ▪ Weight: 10 kg

Stöckli Medical AG · Länggasse 4 · CH-6208 Oberkirch · Phone Direct: 079 214 42 45 · Phone: 041 925 66 55 · www.stoecklimedical.ch

EU Declaration of Conformity

Manufacturer: [redacted]

European Representative:	*Luxus Lebenswelt GmbH*
	Kochstr. 1, 47877, Willich, Germany
DIMDI Code	*DE/0000047791*
Tax Number	*DE305829099*
Contact Person	*Lin Sun*
Tel/Fax	*0049-1715605732*
E-mail	*Info.m@luxuslw.de*

Product Name	*Disposable face mask/Disposable protective mask Disposable Medical face mask*
Test Article	*YY-1, YY-2, YY-3,YY-4,YY-5*

Classification(MDD, Annex VIII) : Class 1,Rule 1

We herein declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.it bears the mark

CE

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN62366-1:2015+AC:2015, ISO 10993- 1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.

13th Dec,2019

Zhao Junpeng /General Manager

[redacted]

Nelson Labs
A Sotera Health company

Sponsor: [redacted]

Synthetic Blood Penetration Resistance Final Report

Test Article:	Disposable medical mask - 1 Disposable medical mask - 2 Disposable medical mask - 3 Disposable medical mask - 4 Disposable medical mask - 5
Study Number:	1289150-S01.1 Amended
Study Received Date:	16 Apr 2020
Study Completion Date:	27 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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.

Number of Test Articles Tested:	32 per test pressure
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	22.2°C and 21% RH

Trang Truong for
Study Director James W. Luskin

07 May 2020
Amended Report Date

1289150-S01

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Amendment Justification: At the request of the sponsor, the company name and address were updated. Additionally, the initial report was separated into individual reports by test pressure.

Nelson Labs
A Sotera Health company

[redacted]

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Disposable medical mask -1 Disposable medical mask - 2 Disposable medical mask - 3 Disposable medical mask - 4 Disposable medical mask - 5
Study Number:	1289157-S01
Study Received Date:	16 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202002111 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Carl Danielson electronically approved for	29 Apr 2020 17:53 (+00:00)
Study Director Robert Putnam	Study Completion Date and Time

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.2	<3	<3	<6.1	<1.9
2	3.1	<3	<3	<5.8	<1.9
3	3.1	<3	<3	<6.1	<2.0
4	3.1	<3	<3	<5.8	<1.9
5	3.1	<3	<3	<6.0	<1.9
Recovery Efficiency	UTD[a]				

< = No Organisms Detected
UTD = Unable to Determine
Note: The results are reported as colony forming units per test article.
[a] UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	88%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Potato Dextrose Agar Tryptic Soy Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 - 7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5 - 7 days at 20-25°C, then enumerated.

Nelson Labs
A Sotera Health company

Sponsor:
[redacted]

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

Test Article:	Disposable medical mask -1 Disposable medical mask - 2 Disposable medical mask - 3 Disposable medical mask - 4 Disposable medical mask - 5
Study Number:	1289151-S02
Study Received Date:	16 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles 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 complies with EN 14683:2019, Annex C and ASTM F2100-19.

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:	Inside
BFE Test Area:	~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
Test Article Dimensions:	~177 mm x ~94 mm
Positive Control Average:	1.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Trang Truong electronically approved for — 19 May 2020 00:42 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.8
2	99.6
3	99.9
4	>99.9
5	99.8

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.4	43.6
2	4.2	41.5
3	4.3	42.1
4	4.7	46.4
5	4.2	41.4

The filtration efficiency percentages were calculated using the following equation:

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

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

[redacted]

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

Sample Description	:	(A)Disposable face mask
SGS Internal Ref No.	:	O-CQAFL202000392405
Sample Color	:	(A)Blue
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 26, 2020
Testing Period	:	Apr 26, 2020 - May 15, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

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Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)*
(EN 14683 :2019 Annex B)

	1#	2#	3#	4#	5#
(BFE), %	99.6	99.6	99.6	99.8	99.7

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR≥98%
* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).

Clause 5.2.3 Breathability (Differential Pressure)
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm²)	34	34	37	36	36

Remark: Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			32				
Overall result:			Acceptable				

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) 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

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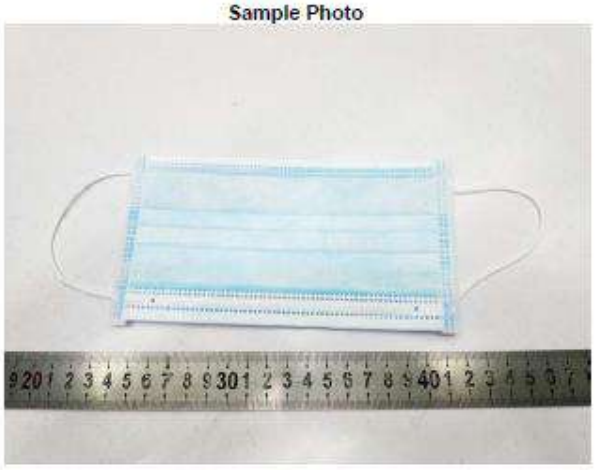
Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D)

Sample A

	1#	2#	3#	4#	5#
CFU/g	1	<1	<1	<1	<1

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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广检集团 GTTC

TEST REPORT (Electronic version)

No:200076624

VERIFICATION WEBSITE: www.gttc.net.cn
VERIFICATION CODE: MFSD-8322-54

ISSUE DATE:2020-04-20

[redacted]

INFORMATION CONFIRMED BY APPLICANT:

ORDINARY PROTECTIVE MASK

QUANTITY: THIRTY-FIVE PIECES

COLOUR: BLUE

DATE RECEIVED/DATE TEST STARTED: 2020-04-14

CONCLUSION:

BACTERIAL FILTRATION EFFICIENCY	M
PARTICLE FILTRATION EFFICIENCY	M
AIRFLOW RESISTANCE	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:
THE DECISION INDICATORS ARE DERIVED FROM THE GROUP STANDARD REQUIRED BY CLIENT (T/CTCA 7-2019). OUR INSPECTION CAPACITY AUTHORIZED BY CMA COVERS THE INSPECTION ITEMS T/CTCA 7-2019.
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200076623.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY: 刘圆
Yuan Liu ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GE2)

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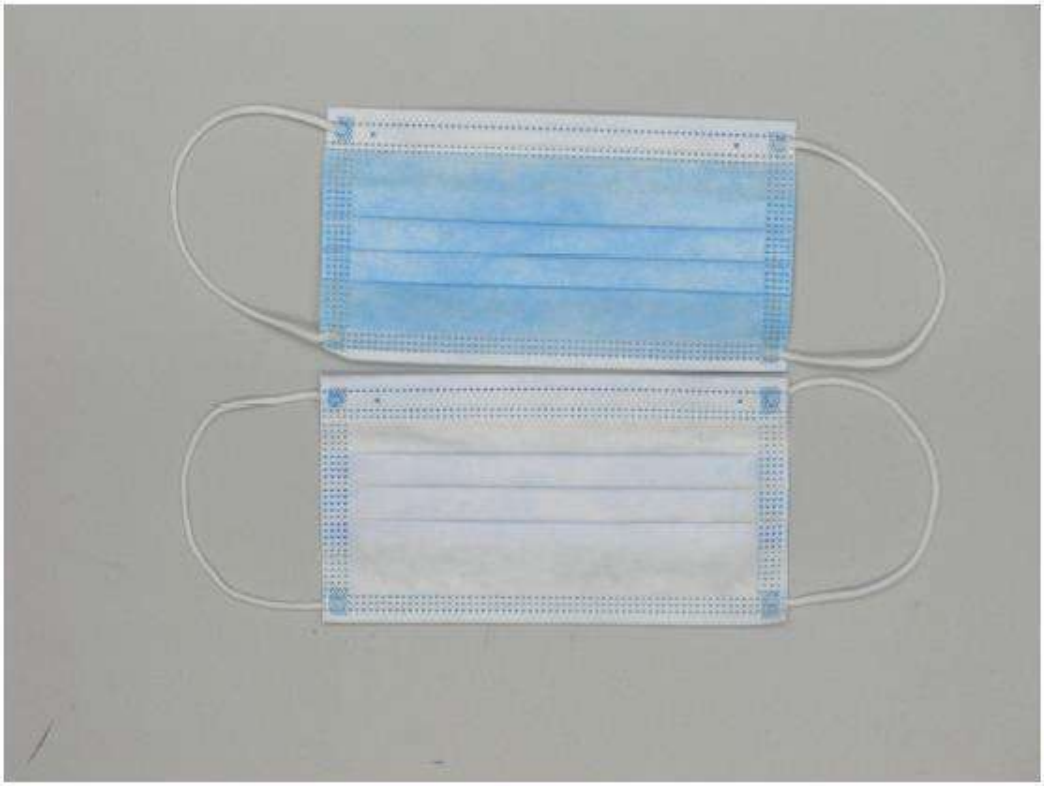
花都实验室：广州市花都区狮岭镇旗岭河宏西路1号
电话:020-61994598/61994599
电话:020-37721161

广检集团
GTTC

TEST REPORT

(Electronic version)

No:200076624



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广检集团 GTTC

TEST REPORT

(Electronic version)

No:200076624

BACTERIAL FILTRATION EFFICIENCY(%)

(YY 0469-2011 ANNEX B, TEST BACTERIA: STAPHYLOCOCCUS AUREUS ATCC 6538, TEST AREA: 40cm^2, FLOW RATE: 28.3L/min, MEAN PARTICLE SIZE: 3.0μm, RESULT OF THE POSITIVE CONTROL: 1.9×10^3 CFU, RESULT OF THE NEGATIVE CONTROL: <1CFU)

		REQUIREMENT
BFE_1	99.6	≥95
BFE_2	99.4	(T/CTCA 7-2019)
BFE_3	99.2	

PARTICLE FILTRATION EFFICIENCY(%)

(YY 0469-2011 5.6.2, AIR FLOW: 30L/min, AEROSOL: NaCl, AEROSOL CONCENTRATION: 15mg/m^3, TEMP: 23.2℃, RH: 36.3%)

		REQUIREMENT
MINIMUM	96.02	≥80
		(T/CTCA 7-2019)

AIRFLOW RESISTANCE(Pa)

(YY 0469-2011 5.6.2, AIR FLOW: 30L/min, AEROSOL: NaCl, AEROSOL CONCENTRATION: 15mg/m^3, TEMP: 23.2℃, RH: 36.3%)

		REQUIREMENT
MAXIMUM	40.0	≤80
		(T/CTCA 7-2019)

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

总部：广州市番禺区珠江路1号
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电话:020-61994598/61994599
电话:020-37721161

GTTC

Test Report (Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: FVMR-0184-54

No:20R000519 Issue Date: 2020-04-24

Applicant: [redacted]
Address:

Information confirmed by applicant:

Disposable medical mask(non-sterile)

Quantity: sixty pieces

Lot number: 042020

Model: YY-101 YY-102 YY-103(submission no.: YY-101)

Size: 175mm×95mm

Classification: Type II R

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-04-09

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	M
Materials and construction	M
Design	M
General	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: Zishan Guo

ZiShan Guo Senior Engineer

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China. Tel: +86-20-61994598 61994599

Test Report

(Electronic version)

No: 20R000519

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

Test Report

(Electronic version)

No: 20R000519

Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

Test principle:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Culture medium: TSA agar medium
Culture temperature: 37℃, Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^{5} CFU /ml
Positive control average (C): 1.9×10^{3} CFU
Negative monitor count: <1 CFU
Test area: 40 cm^2
Dimensions of the test specimens: 15cm×15cm
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

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Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
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Test Report

(Electronic version)

No: 20R000519

Results:

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	9	99.53	≥98 EN 14683:2019+AC:2019	Type IIR	Pass
2	8	99.58			
3	6	99.68			
4	11	99.42			
5	14	99.26			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$B = (C - T) / C \times 100$

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

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Test Report

(Electronic version)

No: 20R000519

Microbial cleanliness
Test method: EN ISO 11737-1:2018, Membrane filtration

Test principle:
Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

Test equipment:
Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

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Test Report

(Electronic version)

No: 20R000519

Results:

Microbial	Measured value (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
Bacteria	0	0	≤30 EN 14683:2019+AC:2019	Type IIR	Pass
Fungi	0				

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Test Report

(Electronic version)

No: 20R000519

Differential pressure
Test method: EN 14683:2019+AC:2019 Annex C

Test principle:
This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:
GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:
Air flow: 8 l/min
Test area: 4.9cm ^{2}
Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
General location of the areas of the mask the differential measurements: specimen center

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Test Report

(Electronic version)

No: 20R000519

Results:

Sample	Measured value (Pa)	Differential pressure (Pa/cm^2)	Requirement (Pa/cm^2)	Classification	Conclusion
1	167	33.7	<60 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	163				
3	172				
4	150				
5	174				
Average	165				

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Test Report

(Electronic version)

No: 20R000519

Splash resistance pressure
Test method: ISO 22609:2004

Test principle:
A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario. Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail". Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa. Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

Test equipment:
Test apparatus for synthetic blood penetration LFY-227
Air compressor
Graduated cylinder
Electronic balance
Targeting plate

The environmental conditions of the laboratory and test condition:
Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Surface tension of synthetic blood: 0.042 N/m
Pressure: 16.0 kPa
Velocity: 550 cm/s

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Inspection & Testing services

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Test Report

(Electronic version)

No: 20R000519

Results:

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0 kPa			
1	pass	≥16.0 EN 14683:2019+AC:2019	Type Ⅱ R	Pass
2	pass			
3	pass			
4	pass			
5	pass			
6	pass			
7	pass			
8	pass			
9	pass			
10	pass			
11	pass			
12	pass			
13	pass			
14	pass			
15	pass			
16	pass			
17	pass			
18	pass			
19	pass			
20	pass			
21	pass			
22	pass			
23	pass			
24	pass			
25	pass			
26	pass			
27	pass			
28	pass			
29	pass			
30	pass			
31	pass			
32	pass			
Final result	pass			

Remarks:

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.

Test Report

(Electronic version)

No: 20R000519

Materials and construction
Test Method: EN 14683:2019+AC:2019 5.1.1

Results:

Requirement	Conclusion
The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Pass
The medical face mask shall not disintegrate, split or tear during intended use.	Pass
In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Pass

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Test Report

(Electronic version)

No: 20R000519

Design

Test Method: EN 14683:2019+AC:2019 5.1.2

Results:

Requirement	Conclusion
The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	Pass
Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	Pass

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Test Report

(Electronic version)

No: 20R000519

General

Test Method: EN 14683:2019+AC:2019 5.2.1

Results:

Requirement	Conclusion
All tests shall be carried out on finished products or samples cut from finished products.	Pass

———End of Report———

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Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

[redacted]

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications:
SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Owner/Operator Number: 10063634

Device Listing#:

Listing No	Code	Device Name
D376832	LYU	ACCESSORY, SURGICAL APPAREL (Mask)

SUNGO Technical 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. SUNGO Technical 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. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

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Sungo global service FDA

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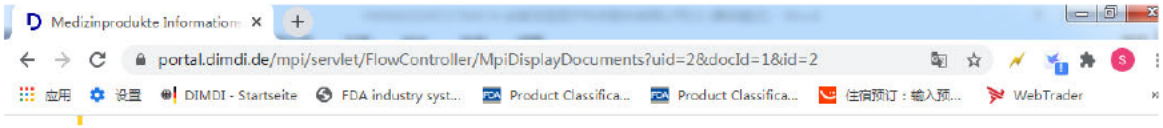
Executive Director
Issued: Mar. 22 2020
Cert. No.: 2007US11518
Expiration Date: Dec. 31 2020



Anzeigen Medizinprodukte (MPA)

zurück weiter

1 von 1 BfArM: MP Anzeigen (MPA) © DIMDI

Dokumentnummer	00162689

Anzeige

Registrierdatum	2020-06-18
Registriernummer	DE/CA20/01-Luxuslebenswelt-468/20
Formblatttyp	Erstanzeige Medizinprodukt
Anzeigender nach § 25 MPG	Bevollmächtigter
Formularnummer	00304496
Frühere Formularnummer	00304496

Angaben zum Anzeigenden

Code	DE/0000047791
Bezeichnung	Luxus Lebenswelt GmbH
Staat	Deutschland
Ort	Willich
Postleitzahl	47877
Straße, Haus-Nr.	Kochstr. 1
Land	Nordrhein-Westfalen
Telefon	0049-1715605732
E-Mail	info.m@luxuslw.de

Zuständige Behörde

Code	DE/CA20
Bezeichnung	Bezirksregierung Düsseldorf
Zusatz	Dezernat 24
Staat	Deutschland
Land	Nordrhein-Westfalen
Ort	Düsseldorf
Postleitzahl	40474
Straße, Haus-Nr.	Cecilienallee 2
Telefon	+49-211-4750
Telefax	+49-211-4752671
E-Mail	dez24.mpg@brd.nrw.de
Bearbeiter	Frau Nadine Schlingmeier
Bearbeiter Telefon	0211-475-3853

Hersteller

Bezeichnung	[redacted]
Staat	
Ort	
Postleitzahl	
Straße, Haus-Nr.	
Telefon	
Telefax	
E-Mail	

Medizinprodukt

Produkttyp	nichtaktives Medizinprodukt
Klasse	I
App (Software auf mobilen Endgeräten)	Nein
Handelsname	Disposable Face mask
Allgemeine Produktbezeichnung	Disposable Face mask
Nomenklaturcode	15-230
Nomenklaturbezeichnung	Maske, sonstige
Kategorie	10 Produkte zum Einmalgebrauch
Kurzbeschreibung	Es kann von Arbeitern in der Umwelt mit hoher Partikelkonzentration getragen werden und kann grundlegende Mikroorganismen und Keime isolieren. Es besteht aus schmelzgeblasenem Stoff und Polypropylen-Vliesstoff.
Kurzbeschreibung in Englisch	It can be worn by workers in the environment with large particle concentration, and can isolate basic microorganisms and germs. It is composed of melt blown cloth and polypropylene non-woven cloth.

Änderungsanzeige | Widerruf

Typ II R with laces Antifog

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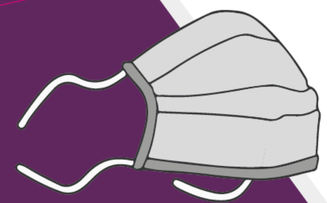
Medizinische Masken Typ II R – EN 14683

Anti-Fog
Typ II R



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Medizinische Masken
Anti-Fog, zum Binden, Typ II R
Masques Médicaux
Anti-buée, fixation à liens, Typ II R
Mascherine Chirurgiche
Anti-nebbia, a nastro, Typo II R
Medical Face Mask
Anti-Fog, tie-on, Type II R

Produkthinweise
- Zum Binden
- Hohe Qualität und Filterleistung
- Hoher Tragekomfort
- Geringer Atemwiderstand
- 100% latex- und fiberglasfrei
- Hypoallergen

Informations sur les produits
- À nouer
- Qualité et performance de filtration élevée
- Confortable à porter
- Résistance respiratoire faible
- 100% sans latex et sans fibre de verre
- Hypoallergénique

Informazioni sul prodotto
- Annodabile
- Alta qualità ed elevate prestazioni del filtro
- Comfort elevato
- Bassa resistenza respiratoria
- Senza lattice e senza fibra di vetro
- Ipoallergenico

Product information
- Tie-on
- High quality and filtration capacity
- High wearing comfort
- Low breathing resistance
- 100% latex-free and fiberglass-free
- Hypoallergenic

Warnhinweise
Diese Maske ist kein Atemschutz. Sie schützt den Träger nicht vor anstecken-den Krankheiten wie Grippe. Nur für den einmaligen Gebrauch. Beschädigte oder mit Körperflüssigkeiten beschmutzte Masken nicht mehr verwenden.

Avertissement
Ce masque n'est pas une protection respiratoire. Il ne protège pas son utilisateur contre les maladies contagieuses telles que la grippe. Seulement à usage unique. Ne pas utiliser les masques endommagés ou souillés de fluides corporels.

Avvertenze
Questa mascherina non è una protezione delle vie respiratorie. Non protegge chi la indossa da malattie contagiose come l'influenza. Solo mascherine sono monouso. Non utilizzare mascherine danneggiate o sporche di fluidi corporei.

Warnings
This mask is not a respirator. It does not protect the wearer from contagious diseases such as the flu. For single use only. Do not use masks that are damaged or soiled with body fluids.

Anwendungsinformationen

Vor dem Anziehen der Maske die Hände mit Seife oder Desinfektionsmittel waschen.

Maske über Nase und Mund legen. Blaue Seite aussen. Der mit Draht verstärkte Teil ist oben über dem Nasenrücken. Die oberen Bänder über die Ohren geführt hinter dem Kopf gut anliegend binden.

Unteren Teil der Maske bis unter das Kinn ziehen und den Nasenbügel in die richtige Passform bringen, sodass die Maske überall eng an der Haut anliegt. Danach die unteren Bänder hinter dem Nacken binden.

Es wird empfohlen, die Maske zu wechseln, wenn sie feucht wird.

Informations sur l'usage

Se laver les mains avec du savon ou du désinfectant avant de mettre le masque.

Mettez le masque de manière à ce qu'il recouvre le nez et la bouche. Côté bleu à l'extérieur. La partie renforcée par du fil de fer doit être placée au-dessus de l'arête du nez. Attachez les bandes bien serrés, au niveau supérieure des oreilles et derrière la tête.

Tirez la partie inférieure du masque jusqu'en dessous du menton et régler le pince-nez afin que le masque s'adapte parfaitement à la peau. Ensuite, attachez les bandes inférieures au niveau de la nuque.

Il est recommandé de changer le masque dès qu'il est mouillé.

Informazioni sull'applicazione

Lavare le mani con sapone o disinfettante prima di indossare la maschera.

Mettere la maschera sul naso e sulla bocca. Laciare la parte blu all'esterno. La parte rinforzata con filo metallico va posta sul dorso del naso. Annodare i lacci presenti sulla parte superiore dietro la testa, all'altezza delle orecchie.

Tirare la parte inferiore della mascherina fino a coprire il mento e regolare la barraetta nasale di modo che la mascherina perfettamente alla pelle. Tirare poi lacci inferiori e annodarli alla base della nuca.

Si bagnata, si consiglia di cambiare la mascherina.

Application Information

Wash hands with soap or disinfectant before putting on the mask.

Put the mask over nose and mouth. Blue side outside. The wire reinforced part is above the bridge of the nose. Tie the upper laces, guided above the ears, behind the head firmly.

Pull the lower part of the mask up to under the chin and adjust the nose bar to the correct fit so that the mask fits tightly against the skin everywhere. Then tie the lower tapes behind the neck.

It is recommended to change the mask as soon as it becomes wet.

Leistungsanforderungen für Medizinische Masken
Exigences de performance pour les Masques Médicaux
Requisiti di prestazione per le Mascherine Mediche
Performance requirements for Medical Masks

Klassifizierung / Classification / Classificazione / Classification		Type I	Type II	Type II R
Bakterielle Filterleistung / Efficacité de filtration bactérienne / Prestazioni del filtro batterico / Bacterial Filtration Efficiency	BFE	≥ 95 %	≥ 98 %	≥ 98 %
Druckdifferenz / Pression différentielle / Differenza di pressione / Differential pressure	pa/cm²	< 40	< 40	< 60
Druck des Spritzwiderstands / Pression de la résistance aux pulvérisations / Pressione della resistenza agli spruzzi / Splash Resistance Pressure	kPa	– *	– *	≥ 120*
Mikrobiologische Reinheit / Propreté microbienne /Purezza microbiologica / Microbial cleanliness	cfu/g	≤ 30	≤ 30	≤ 30

* Typ II R ist ein flüssigkeitsresistenter Typ. / Le type II R est un type résistant aux liquides / Tipo II R è un tipo resistente ai liquidi. / Type II R is a liquid resistant type.

Die in dieser Verpackung enthaltenen medizinischen Masken dienen vor allem dem Fremdschutz und schützen das Gegenüber des Maskenträgers vor der Exposition möglicher infektiöser Tröpfchen. Primäre Zweckbestimmung: Anwendung im medizinischen Umfeld um die Patienten zu schützen. Diese medizinischen Masken schützen bei festem Sitz begrenzt auch den Träger der Maske, dies ist jedoch nicht die primäre Zweckbestimmung.

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Medizinische Masken
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Masques Médicaux
Anti-buée, fixation à liens, Typ II R
Mascherine Chirurgiche
Anti-nebbia, a nastro, Typo II R
Medical Face Mask
Anti-Fog, tie-on, Type II R

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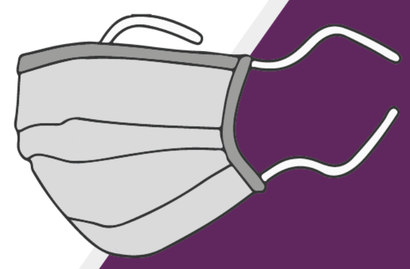

Medizinische Masken Typ II R – EN 14683

Anti-Fog
Typ II R

REF AN-00-2-R
LOT
12-2020
12-2023

Produkt Medizinische Masken Typ II R, EN14683:2019, 3-Schichten, Anti-Fog, zum Binden
Masques Médicaux Type II R, EN14683:2019, 3-plis, Anti-buée, fixation à liens
Mascherine Chirurgiche Tipo II R, EN14683:2019, 3-strati, Anti-nebbia, a nastro
Medical Face Mask Type II R, EN14683:2019, 3-layers, Anti-Fog, tie-on

Mascarilla quirurgica / Medische maskers
Medicinska masker / Medicinske maske
Medicinska masker / Orvosi maszkok

Importeur Stöckli Medical AG, Länggasse 4, CH-6208 Oberkirch
info@stoecklimedical.ch, +41 41 925 66 55

[redacted]

EC REP Luxus Lebenswelt GmbH, Kochstrasse 1, 47877, Willich, Germany

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