
HYGISUN
Medical Face Mask (Non-Sterile)
50 PCS
REF HS0401A
HYGISUN
Medical Face Mask (Non-Sterile)
EARLOOP, BLUE
Gesichtsmaske, 3-lagig
LOT:20200715
MFG:20200715
EXP:20220715
50 PCS
20 bcs
Ear strap on both ears
Press down around nose
Pull down mask to cover jaw
4 260676 530010


HYGISUN
Medical Face Mask (Non-Sterile)
EARLOOP, BLUE
Gesichtsmaske, 3-lagig
REF HS0401A
50 PCS
Latex Free
3-layer
Single Use
FIRST PLY
NON-WOVEN FABRIC
MIDDLE PLY
FILTER PAPER (MELT BLOWN FABRIC)
THIRD PLY
NON-WOVEN FABRIC
Made in China
EN 14683 Type II


HYGISUN
Medical Face Mask
Sichuan Ai Doctor Medical Technology Co.,Ltd
333 Yongke Road,Yongsheng town,Wenjiang District,
Chengdu City,Sichuan Province, China
EC REP
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam,Netherlands
Storage method: Masks shall be stored in a clean,ventilated and dry warehouse,with a temperature -10℃ and a relative humidity ≤80%.
Precautions： It is recommended to replace it every 2-4 hours, once it is contaminated, it should be replaced as soon as possible;
SIZE: 17X9.5CM
Made in China
EN 14683 Type II

HYGISUN

REF HS0401A

Medical Face Mask

Earloop.Blue

EN14683 Type II

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
R.A.C. Ori

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20202302

Bijlagen
-

Uw aanvraag
19 mei 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 29 mei 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 19 mei 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Sichuan Ai Doctor Medical Technology Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Surgical Mask (Non-sterile)
(geen merknaam) (NL-CA002-2020-51493)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

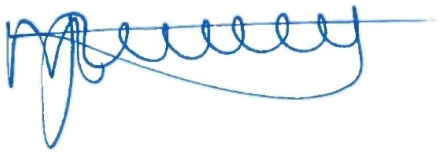
Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

zer niet gedefinieerd.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC) including Directive 2007/47/EC

Manufacturer: . Sichuan Ai Doctor Medical Technology Co., Ltd

Address: No.333, Yongke Roade, Yongsheng Town, Chengdu Cross-strait Science and Technology Industrial Development Park, Wenjiang District, Chengdu, Sichuan, China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam,Netherlands

Product Name: Surgical mask (Non-sterile)

Specification: Earloop Type 170*95MM

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)

Conformity Assessment: Annex VII

CE

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN 14683:2019

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Signature:

Date: 2020 年 5 月 15 日

Authorized Signature (S)

171021110579

检验检测报告

TEST REPORT

STFWT20201056

产品名称 Product Name	一次性使用日用口罩
委托单位 Trust Unit	四川艾医生医疗科技有限公司
生产单位 Manufacturer	四川艾医生医疗科技有限公司
检验检测类别 Test Category	委托送样检验

江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检 验 检 测 报 告

Test Report

防伪查询

STFWT20201056

产品名称 Product Name	一次性使用日用口罩	规格型号 Specification Type	挂耳型 170mm*95mm
		商 标 Trademark	敏甄™
委托单位 Trust Unit	四川艾医生医疗科技有限公司	电 话 Tel	18215607950
生产单位 Manufacturer	四川艾医生医疗科技有限公司	样品等级 Sample Grade	KN90
样品数量 Sample Quantity	30 只	送样日期 Sample Receiving Date	2020-02-17
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	MY20200201
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	YY/T0969-2013《一次性使用医用口罩》 GB/T32610-2016《日常防护型口罩技术规范》		
检验检测结论 Test Conclusion	样品经检验，符合 GB/T32610-2016 和YY/T0969-2013 标准规定的要求。 签发日期： 2020-02-26 SignatuimDate		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批 准： 颁海燕 Approver　　审 核： 吴高高 Examiner　　主 检： 蔡燕文 Majortester

检 验 检 测 结 果
Testing Results

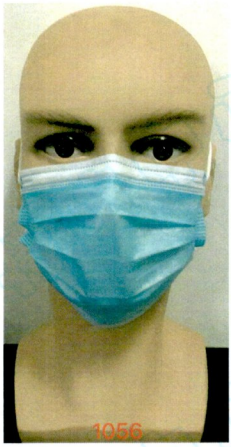
STFWT20201056

序号 Serial	检验检测项目 Test Items		单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	外观		——	口罩外观应整洁，形状完好，表面不得有破损、污渍。	口罩外观整洁，形状完好，表面未有破损、污渍。	合 格
2	结构与尺寸		——	口罩佩戴好后，应能罩住佩戴者的鼻、口至下颌。应符合设计的尺寸，最大偏差应不超过±5%。	口罩佩戴好后，能罩住佩戴者的鼻、口至下颌。符合设计的尺寸	合 格
3	鼻夹		——	1、口罩上应配有鼻夹，鼻夹由可塑性材料制成。 2、鼻夹长度应不小于8.0cm。	1、口罩上配有鼻夹，鼻夹由可塑性材料制成。 2、鼻夹长度： 9.3cm、9.4cm、9.5cm。	合 格
4	口罩带		——	1、口罩带应戴取方便。 2、每根口罩带与口罩体连接点处的断裂强力应不小于10N。	1、口罩带戴取方便。 1#：试样断裂强力不小于10N 2#：试样断裂强力不小于10N 3#：试样断裂强力不小于10N	合 格
5	细菌过滤效率/%（BFE）		——	≥95	97.1	合 格
6	微生物指标	细菌菌落总数	CFU/g	≤100	4	合 格
		大肠菌群	——	不得检出	未检出	
		金黄色葡萄球菌	——	不得检出	未检出	
		绿脓杆菌	——	不得检出	未检出	
		溶血性链球菌	——	不得检出	未检出	
		真菌	——	不得检出	未检出	

检 验 检 测 结 果
Testing Results

样 品 图 片

测试样品



以下空白

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[redacted]

52146 Würselen

Deutschland

Akkreditierte Prüfstelle nach ÖNORM EN ISO 17025

Bischofshofen, 25.05.2020

Prüfbericht / *test report* B 24090

Labor-Nr. / *identification of the test laboratory:*	B 24090
Prüfprodukt / *test product*:	Maske HS0401A Hygisun
Auftraggeber / *ordered by*:	[redacted]
Auftragsdatum / *date of order*:	2020-04-28
Materialeingang / *date of delivery*:	2020-05-04
Prüfzeitraum / *period of analysis*:	2020-05-11 bis / *to* 2020-05-25
Prüfbedingungen / *test conditions:*	Die Prüfung erfolgte im Anlieferungszustand. / *The test was done in the delivery state.*
Prüfauftrag / *test order:*	Medizinische Gesichtsmasken - Anforderungen und Prüfverfahren / *Medical face masks - Requirements and test methods* EN 14683:2019
Prüfmethoden / *test methods*:	SOP 13-002 Bakteriellen Filtrationsleistung (BFE) / *bacterial filtration efficacy (BFE)* EN 14683 Anhang / *annex* B SOP 13-001 Atmungs-Eignungsprüfung, differentialer Druck / *breathability test, differential pressure* EN 14683 Anhang / *annex* C SOP 07-014 Mikrobiologische Reinheit / *Determination of a population of micro-organisms* EN ISO 11737-1

Ergebnis der Prüfung der Filterwirksamkeit für Bakterien für Masken / *test results of bacterial filtration efficacy of masks*
EN 14683 / SOP 13-002

Information: 5.2.2 der EN 14683:2019+AC

Prüfprodukt / *test product*:	Maske HS0401A Hygisun
Prüfdatum / *date of testing*:	2020-05-12
Anzahl der Prüfkörper / number of samples:	5
Volumenfluss / *volume flow:*	28.3 l/min
Größe der Prüfkörper / *sample size*:	10cm x 10cm
Geprüfter Bereich des Prüfkörpers / *sample area tested:*	50 cm²
Prüfkeim / *test strain*:	*Staphylococcus aureus* ATCC 6538
KBE der Ausgangskeimsuspension / *cfu of test suspension:*	5,72 x 10^5/ml
Inkubation / *incubation:*	48 h bei / *at* 36 ± 1 °C
Raumtemperatur / *room temperature*:	20 °C
Luftfeuchte / *relative humidity*:	40 %

Ergebnis der Prüfung der Filterwirksamkeit für Bakterien für Masken / *test results of bacterial filtration efficacy of masks*
EN 14683 / SOP 13-002

Gezählte KBE/Platte / *counted cfu per plate*

	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
PK1	217	298	321	357	342	298	**1833**
PK2	198	216	302	376	301	317	**1710**
NK	0	0	0	0	0	0	**0**

Gezählte KBE/Platte nach Umrechnung mit „Positive hole conversion table“ /
Counted cfu per plate after conversion with “positive hole conversion table”

	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
PK1	217	298	649	892	772	547	**3375**
PK2	198	216	583	1125	559	629	**3310**
NK	0	0	0	0	0	0	**0**

Gezählte KBE/Platte / *counted cfu per plate*

Probe / *sample*	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
1	12	5	5	6	7	24	**59**
2	5	1	5	2	4	21	**38**
3	6	6	3	5	5	15	**40**
4	3	6	2	8	13	26	**58**
5	11	5	6	9	7	21	**59**

Gezählte KBE/Platte nach Umrechnung mit „Positive hole conversion table“ /
Counted cfu per plate after conversion with “positive hole conversion table”

Probe / *sample*	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
1	12	5	5	6	7	25	**60**
2	5	1	5	2	4	22	**39**
3	6	6	3	9	5	15	**44**
4	3	6	2	8	13	27	**59**
5	11	5	6	9	7	22	**60**

Legende / *legend*:

KBE / cfu	=	Kolonie bildende Einheiten / *colony forming units*
PK	=	Positivkontrolle / *positive control*
NK	=	Negativkontrolle / *negative control*

Bewertung der Filterwirksamkeit / *rating of bacterial filtration efficacy*
EN 14683 / SOP 13-002

Probe / *sample*	Filterwirksamkeit *filtration efficacy* [%]
1	98,20
2	98,83
3	98,68
4	98,23
5	98,20
Mittelwert *mean value*	**98,52**

Berechnungsformel / *calculation formula*: $B = \frac{(C - T)}{C \times 100}$

C = Mittelwert der gesamten Plattenauszählung für die beiden positiven Kontrolläufe
plate count average of both positive control runs
T = gesamte Plattenauszählung für das Prüfstück
total plate count of the sample

Ergebnis der Atmungs-Eignungsprüfung, differentialer Druck, in Übereinstimmung mit U. S. Militär-Spezifikation-MIL-M-36954 C (Luft-Austausch-druck) / *breathability test result, differential pressure, in accordance with U.S. Military Specification MIL-M-36954 C (Air Exchange Pressure)*
EN 14683 / SOP 13-001

Information: 5.2.3 der EN 14683:2019+AC

Prüfprodukt / *test product*:	Maske HS0401A Hygisun
Prüfdatum / *date of testing*:	2020-05-18
Anzahl der Prüfkörper / number of samples:	5
Anzahl der Prüfungen pro Prüfkörper / *number of tests per sample:*	5
Größe der Prüfkörper / *sample size*:	10cm x 10cm
Geprüfter Bereich des Prüfkörpers / *sample area tested:*	kreisförmig, Durchmesser 2,5 cm / *circular, diameter 2.5 cm*
Geprüfter Bereich des Prüfkörpers / *tested area of the test sample*:	4.9 cm²
Luftstrom / *airflow*:	8 l/min ± 0.2 l
Raumtemperatur / *room temperature*:	20 °C
Luftfeuchte / *relative humidity*:	48 %
Standardabweichung / *standard deviation:*	1,19

Probe / *sample*	Pos. 1 Pa	Pos. 2 Pa	Pos. 3 Pa	Pos. 4 Pa	Pos.5 Pa	Mittelwert / *mean value* Pa	ΔP [Pa/cm²]
1	178,90	133,90	157,90	168,90	112,30	**150,38**	**30,69**
2	107,70	198,50	182,30	145,90	139,50	**154,78**	**31,59**
3	138,50	168,90	164,50	101,30	116,80	**138,00**	**28,16**
4	124,50	132,50	110,30	157,80	191,20	**143,26**	**29,24**
5	143,60	178,60	156,30	127,10	113,70	**143,86**	**29,36**
Mittelwert / *mean value*							**29,81**

Legende / *legend*:
Pa = Pascal

Berechnungsformel / *calculation formula* = Differentialdruck / *differential pressure* $\Delta P = \frac{\bar{x}\,m_2 - \bar{x}\,m_1}{4{,}9}$

Bestimmung der Population von Mikroorganismen auf Produkten, Mikrobiologische Reinheit / *Determination of a population of micro-organisms on products*
EN ISO 11737-1 / SOP 07-014

Information: 5.2.5 der EN 14683:2019+AC

Ergebnis der Validierung des Ablösungsverfahrens mittels wiederholender Rückgewinnung / *Result of the validation of the elution procedure using the method of repeated recovery*

Prüfprodukt / *test product*:	Maske HS0401A Hygisun
Prüfdatum / *date of testing*:	2020-05-11
Probengewicht / *sample weight*:	3.59 g
Ablösungsverfahren / *dissolution procedure*:	1 Maske wurde bei höchster Stufe im Stomacher 5 min mit Verdünnungslösung eluiert / *1 mask was processed 5 min in a stomacher by highest speed with dilution solution*
Raumtemperatur / *room temperature*:	22.0 °C
Luftfeuchte / *relative humidity*:	41 %
Inkubation / *incubation*:	Bebrütung des Membranfilters auf Blutagar, / *Incubation of the membrane filter on blood agar,* 48h bei / *at* 36 ±1°C

Anzahl Tests / *number of tests*	**Volumen Eluierungsmittel / *volume elution medium***	**KBE / Prüfkörper / *cfu / test body***
1a	20 ml	2
1b	20 ml	2
1c	20 ml	17
1d	20 ml	6

Berechnung der Ergebnisse / *calculation of the results*

Ablösung / *dissolution* in %: 7.41 %

Korrekturfaktor / *correction factor:* 13.50

Legende / *Legend*:
VF = Verdünnungslösung / *dilution solution* (0.85% NaCl, 0.1% Trypton)
KBE / cfu = Kolonie bildende Einheiten / *colony forming units*

$$\text{Ablösung / } \textit{dissolution in } \% = \frac{\text{Anzahl der Mikroorganismen nach der 1. Eluierung / } \textit{number of micro-organisms after the 1. elution}}{\text{Anzahl der Mikroorganismen von Eluierung 1 – 4 / } \textit{number of micro-organisms after elution 1 – 4}} \times 100$$

$$\text{Korrekturfaktor / } \textit{correction factor:} = \frac{100}{\text{Ablösung / } \textit{dissolution in } \%}$$

Bestimmung der Population von Mikroorganismen auf Produkten, Mikrobiologische Reinheit / *Determination of a population of micro-organisms on products*
EN ISO 11737-1 / SOP 07-014

Prüfprodukt / *test product*:	Maske HS0401A Hygisun
Prüfdatum / *date of testing*:	2020-05-11
Probengewicht / *sample weight*:	3.59 g
Ablösungsverfahren / *dissolution procedure*:	1 Maske wurde bei höchster Stufe im Stomacher 5 min mit Verdünnungslösung eluiert / *1 mask was processed 5 min in a stomacher by highest speed with dilution solution*
Raumtemperatur / *room temperature*:	22.0 °C
Luftfeuchte / *relative humidity*:	41 %
Inkubation / *incubation*:	Bebrütung des Membranfilters auf Blutagar, / *Incubation of the membrane filter on blood agar,* 48h bei / *at* 36 ±1°C
Korrekturfaktor / *correction factor:**	13.50

Nr. / *No.*	**Nährboden / *medium***	**Gesamtkeimzahl / KBE / PK *total count cfu / PK***	**Mikrobiol. Differenzierung / *microbiol. Differentation***	**Gesamtkeimzahl x Korrekturfaktor *total count x correction factor****	**KBE / g *cfu / g***
Test 2	Blutagar / *blood agar*	4	-	54.00	15.04
Test 3	Blutagar / *blood agar*	2	-	27.00	7.52
Test 4	Blutagar / *blood agar*	6	-	81.00	22.56
Test 5	Blutagar / *blood agar*	1	-	13.50	3.76
Test 6	Blutagar / *blood agar*	3	-	40.50	11.28

Grenzwerte / *Critical values*:

Aerobe mesophile Keimzahl / *aerobe mesophile germ number*	<1000 KBE / *cfu*
Hefen und Schimmelpilze / *yeasts and moulds*	<100 KBE / *cfu*
Staphylococcus aureus	<10 KBE / *cfu*
Sterptococcus	<10 KBE / *cfu*
Pseudomonaden	<10 KBE / *cfu*
Enterobacteriaceae	<10 KBE / *cfu*

Ergebnis/ *Result*: 12,03 KBE/g

Legende / *Legend*:

VF	=	Verdünnungslösung / *dilution solution* (0.85% NaCl, 0.1% Trypton)
KBE / *cfu*	=	Kolonie bildende Einheiten / *colony forming units*
PK	=	Prüfkörper / *test body*
n	=	nicht zählbar / *not countable*

Schlussfolgerung / *conclusion*:

Die überprüfte Maske Maske HS0401A Hygisun entspricht den Vorgaben der EN 14683:2019, für Masken des Typs II.

The tested mask Maske HS0401A Hygisun fulfils the requirements of EN 14683:2019, for type II masks.

Archivierung / *Archiving:* Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv der HygCen Austria GmbH aufbewahrt. / *A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.*

Hinweis / *Note*: Der vorliegende Prüfbericht bezieht sich ausschließlich auf die dem Labor vorliegenden Prüfgegenstände. Jede auszugsweise Vervielfältigung bedarf der schriftlichen Genehmigung durch die HygCen Austria GmbH. / *The present test report refers exclusively to the test objects available to the laboratory. Any duplication in extracts requires the written permission of HygCen Austria GmbH.*

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Technischer Leiter / *technical manager*

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Stellvertretender technischer Leiter / *vice technical manager*

Anhang zum Prüfbericht B 24090
attachment to test report B 24090

Abb. 1: Maske HS0401A Hygisun

Anhang / *attachment*
Erläuterung zum Prüfbericht B 24090
Comment to test report B 24090

1. Leistungsanforderungen für chirurgische Masken entsprechend / *performance requirements for surgical masks* EN 14683:2019

Prüfung / *test*	**Typ / *type* I**	**Typ / *type* II**	**Typ / *type* IIR**
Bakterielle Filterleistung / *bacterial filtration efficiency* (BFE) %	≥ 95	≥ 98	≥ 98
Druckdifferenz / *differential pressure* Pa	<40	<40	<60
Mikrobiologische Reinheit / *bioburden* (g)	≤ 30	≤ 30	≤ 30

2. Verfahren für die in-vitro Bestimmung der bakteriellen Filterleistung / *method for in vitro determination of bacterial filtration efficiency* (BFE)

Historie / *history*
Der Aufbau der Prüfung der Filterwirksamkeit für Bakterien für Masken wurde erstmals in der Militär-Spezifikation MIL-M-36954C *„Mask, Surgical, Disposable“* aus dem Jahr 1975 beschrieben.
Seitdem wurde die Prüfung der Filterwirksamkeit in weiteren internationalen Normen umgesetzt:

von EDANA (European Disposables And Nonwovens Association) und INDA (Association of Nonwoven Fabrics Industry) in WSP 300.0 (05) *„Standard Test Method for Nonwovens Bacterial Filtration Efficiency“*,

von ASTM (American Society for Testing and Materials) in ASTM F 2101-07 *„Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus“* und

von CEN (Europäischen Normungskommission) in EN 14683 *“Chirurgische Masken – Anforderungen und Prüfverfahren”.*

The structure of the test method of the bacterial filtration efficiency for surgical masks was described for the first time in military specification MIL-M-36954C "Masks, Surgical, Disposable" from the year 1975. Since then the testing of the bacterial filtration efficiency was converted into further international standards:

by EDANA (European Disposables and Nonwovens Association) and INDA (Association OF Nonwoven Fabrics Industry) in WSP 300,0 (05) "standard test Method for Nonwovens Bacterial filtration Efficiency",

by ASTM (American Society for Testing and of material) in ASTM F 2101-07 "standard test Method for Evaluating the Bacterial filtration Efficiency (BFE) OF Medical Face MASK of material, Using A Biological aerosol OF Staphylococcus aureus"

and by the CEN (European standardization commission) in EN 14683 "surgical masks - requirements and testing methods".

Testprinzip / *test principle*
Eine Probe des Maskenmaterials wird zwischen ein sechsstufiges Kaskaden-Aufprallgerät (Andersen Sampler) und eine Aerosolkammer eingeklemmt. In die Aerosolkammer wird ein Aerosol von *Staphylococcus aureus* eingeführt und unter Vakuum durch das Maskenmaterial und das Aufprallgerät gezogen.
Die bakterielle Filterleistung der Maske wird durch die Anzahl der koloniebildenden Einheiten angegeben, die durch die Maske hindurchgehen, angegeben als Prozentsatz der im Belastungsmaterial vorliegenden koloniebildenden Einheiten.

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 of the mask is given by the number of colony forming units passing through the surgical mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Auswertung der Prüfung / *evaluation of the examination*
Es wird eine Umrechnung der Keimzahlen auf den Ebenen 3-6 des sechsstufigen Kaskaden-Aufprallgerätes mit der „positive hole conversion table“ von Andersen A. A. (1958) durchgeführt.

The colony forming units on the levels 3-6 of the six-level cascade impact are converted with the "positive hole conversion table" described by Andersen A. A. (1958).

3. Verfahren zur Bestimmung der Atmungsaktivität (Druckdifferenz) / *method for the determination of the breathability (differential pressure)*

Testprinzip / *test principle*
In einem Versuchsaufbau wird die Druckdifferenz gemessen, indem Luft bei einem Luftstrom von 8l/min durch eine definierte Grundfläche des Materials gezogen wird.

Die Druckdifferenz wird mit einem Druckmessmodul gemessen. Gilmont-Instrumente-Flowmeter oder ein Flowmeter von vergleichbarer Präzision werden für die Messung des Luftstroms benutzt. Das Probenmaterial wird zwischen die Prüfflächen geklemmt, so dass das Probenmaterial quer zum Luftdurchfluss in der Strömung platziert ist. Die Vakuumpumpe wird eingeschaltet und die Durchflussrate der Luft wird am Flowmeter über ein Nadelventil auf 8l/min eingestellt. Durch das Druckmessmodul wird der Druck m1 und m2 gemessen und aufgezeichnet.

Dieses Verfahren wird an 5 unterschiedlichen Stellen der Materialien angewendet und der Mittelwert ermittelt.

In an experimental setup the differential pressure is measured, as air is pulled with an air flow by 8l/min through a defined surface area of the material.

The differential pressure is measured with a pressure measuring module. Gilmont-Instrumente-Flowmeter or a flowmeter of comparable precision are used for the measurement of the air flow. The sample material is wedged between the test surfaces, so that the sample material is placed transverse to the air flow. The vacuum pump is switched on and the flow rate of air is adjusted

at the flowmeter over a needle valve to 8l/min. The pressure m1 and m2 is measured and noted with the pressure measuring module.

This procedure will be performed at 5 different places of the materials and the mean value is determined.

SUBJECT	**Physical & Microbiological Test**
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TEST PERIOD	26-Apr-2020~08-May-2020

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TEST REPORT

Sample Description	:	Surgical Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	20200401
Specification	:	Earloop Type
Size	:	/
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type ⅡR	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm^2)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 98.2% Specimen 2#: 98.0% Specimen 3#: 98.1% Specimen 4#: 98.1% Specimen 5#: 98.1%
2	Differential Pressure Test	26.6 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 1 CFU/g Specimen 3#: <1 CFU/g Specimen 4#: <1 CFU/g Specimen 5#: <1 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Surgical Mask
Specification : Earloop Type
Lot Number : 20200401
Sample Receiving Date : 2020-04-26

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

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

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	53	98	0	0	0	0	1	1
2	112	136	0	2	1	1	2	1
3	130	165	0	1	1	2	6	1
4	213	298	0	3	1	6	7	6
5	1518	1518	0	26	29	27	27	29
6	434	475	0	16	19	13	7	12
Total (*T*), CFU	2460	2690	<1	48	51	49	50	50
Average (C), CFU	$2.6 \times 10^3 = (P_A + P_B) / 2$							
BFE ,%				98.2	98.0	98.1	98.1	98.1
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description	:	Surgical Mask
Specification	:	Earloop Type
Lot Number	:	20200401
Sample Receiving Date	:	2020-04-26

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average (Pa/cm^2)	Requirements	Judgement
1#	27.4	26.6	< 60	Pass
2#	29.1			
3#	22.6			
4#	27.5			
5#	26.5			

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Surgical Mask
Specification	:	Earloop Type
Lot Number	:	20200401
Sample Receiving Date	:	2020-04-26

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 32 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(ρ is the density of the test fluid.) $t = 0.5 + (2\times \rho$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen		Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	Surgical Mask
Specification	:	Earloop Type
Lot Number	:	20200401
Sample Receiving Date	:	2020-04-26

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um 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 SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	0	<1	EN14683:2019+AC:2019(E) Annex D EN ISO 11737-1:2018 ≤ 30 CFU/g	Pass
2#	0	1	1		
3#	0	0	<1		
4#	0	0	<1		
5#	0	0	<1		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

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