MEDISCH / CHIRURGISCH MASKER 3-LAYERS

Hoogwaardige medische maskers met goedgekeurd CE-certificaat volgens Europese norm EN 14683.


Review Report –申报告–검토 보고서– Rapport d'Evaluation

CE Documentation Review

No. 4M200312.TSSU054

Holder: TAIZHOU SAFE SECURE MEDICAL MANUFACTURER CO., LTD.
Century Way Kowloon Town Jiangsu Province China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable medical mask **(no sterile)**
Model(s): 21.5*9.5, 18*9.5, 17.5*9.5, 16.5*9.5, 14.5*9, 12.5*9

Classification: Class I (no sterile)
according to the Manufacturer's declaration

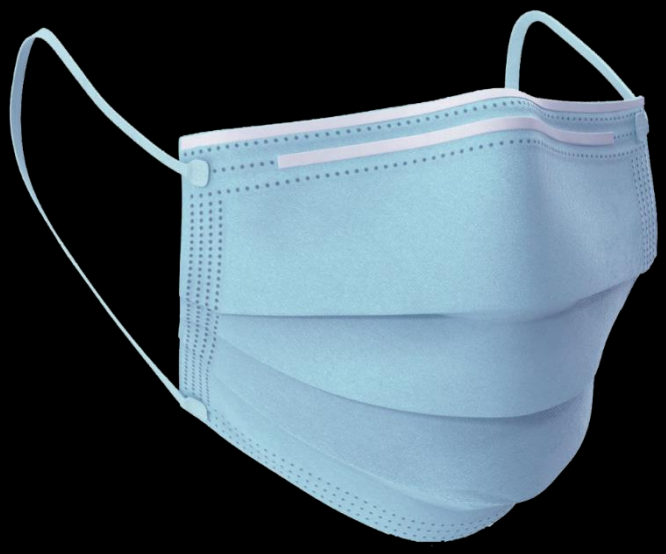
Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Test Report identified with the no. RTS-2019194. The document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 12 March 2020 — Expiry date 11 March 2025

Service Manager — Deputy Manager

Ente Certificazione Macchine

Certificaat Nr. 4M200312.TSSU054



MEDISCH / CHIRURGISCH MASKER

99% filter systeem

MEDISCH / CHIRURGISCH MASKER 3-LAYERS

VOOR

Effectieve filterstof

ACHTER

Sneller filtersysteem
Lichter en beter ademend

DETAILS

Verborgen verstelbare neusclip

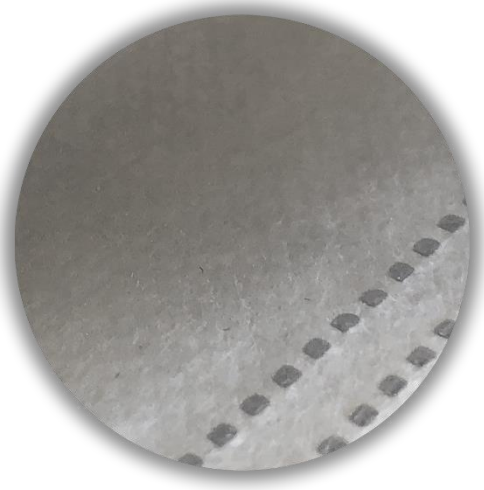
CLOSE UP

Er worden hoogwaardige materialen gebruikt.

DETAILS

Verborgen verstelbare neusclip

Met geïntegreerd filtermedium zodat het product een hoog antibacterieel filtereffect biedt terwijl de drager normaal kan blijven ademen.



Perfecte randen die ervoor zorgen dat de 3 lagen goed vast zitten en minder snel loskomen.

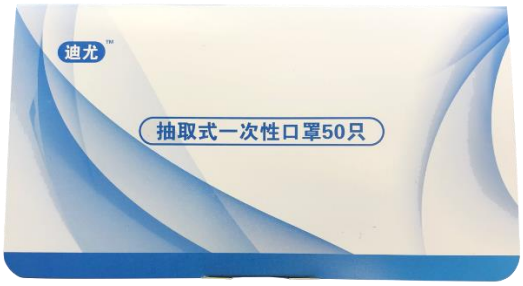
MEDISCH / CHIRURGISCH MASKER 3-LAYERS

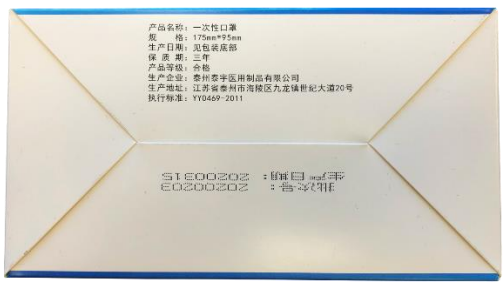
Goed verpakt in een omdoos van 50 stuks.

Afmeting van het product: 175 mm * 95 mm

Grootte van de buitenste doos: 183 mm * 100 mm * 103 mm

MEDISCH / CHIRURGISCH MASKER 3-LAYERS





CE - CERTIFICATE

Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

CE Documentation Review

No. 4M200312.TSSU054

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Classification:	Class I (no sterile) (accordingly to the Manufacturer's declaration)
Review output:	We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Test Report identified with the no. BTS-20189M. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 12 March 2020

Service Manager
Luca Pedrini

Expiry date 11 March 2025

Deputy Manager
Amanda Bayne

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TEST RAPPORT

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FINAL REPORT

BACTERIAL FILTRATION EFFICIENCY (BFE)/
DIFFERENTIAL PRESSURE (ΔP) TESTS

PROCEDURE NO. SOP/ARO/007J.1

LABORATORY NO. 246885

PREPARED FOR:

TAIZHOU SAFE SECURE MEDICAL MANUFACTURER CO., LTD.
CENTURY WAY, KOWLOON TOWN
JIANGSU PROVINCE,
P.R. CHINA

SUBMITTED BY:

NELSON LABORATORIES, INC.
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UNITED STATES OF AMERICA
801-963-2600

TEST RAPPORT

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BACTERIAL FILTRATION EFFICIENCY (BFE)/ DIFFERENTIAL PRESSURE (ΔP) TESTS

LABORATORY NUMBER:	246885
PROCEDURE NUMBER:	SOP/ARO/007J.1
SAMPLE SOURCE:	R & T Management Consultancy Services, Inc.
SAMPLE IDENTIFICATION:	Non Woven Face Masks
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
SAMPLE RECEIVED DATE:	29 Sep 2003
LAB PHASE START DATE:	02 Oct 2003
LAB PHASE COMPLETION DATE:	05 Oct 2003
REPORT ISSUE DATE:	07 Oct 2003
TOTAL NUMBER OF PAGES:	9

INTRODUCTION:

This test procedure was performed to determine the bacterial filtration efficiency (BFE) of various filtration materials, employing a ratio of the bacterial challenge counts to sample effluent counts, to determine percent BFE. This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This test procedure allowed a reproducible bacterial challenge to be delivered to test materials. This procedure has been used with little or no modifications and provides a standard procedure for comparison of filtration materials.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of the porous materials. The technique involved a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

ACCEPTANCE CRITERIA:

The BFE control average must be 2200 ± 500 CFU. A BFE run with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 3000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 shall be at sponsor's approval.

The mean particle size (MPS) of the challenge aerosol must be maintained at 3.0 ± 0.3 μm.

The average % BFE for the reference material must be within the upper and lower control limits established for the BFE test.

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The average Delta P result for the reference material must be within the upper and lower control limits established for the Delta P test.

SAMPLE PREPARATION:

BFE test samples were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity prior to testing.

TEST PROCEDURE:

A culture of *Staphylococcus aureus* ATCC #6538 was diluted in 1.5% peptone water to a precise concentration to yield challenge level counts of 2200 ± 500 colony forming units (CFU) per test sample. The bacterial culture suspension was pumped through a Chicago nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a mean particle size (MPS) of approximately 3.0 μm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 Lpm (1 CFM). Test controls and test samples were challenged for a two minute interval.

The delivery rate of the challenge also produced a consistent challenge level of 2200 ± 500 CFU on the test control plates. A test control (no filter medium in the airstream) and reference material are included after 5-10 test samples. The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six agar plates based on the size of each droplet. The agar medium used was soybean casein digest agar. The agar plates were incubated at 37 ± 2°C for 45 hours and the colonies formed by each bacteria laden aerosol droplet counted and converted to probable hit values using the hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates were used to calculate the MPS of the challenge aerosol.

RESULTS:

The results are summarized in Table 1.

The filtration efficiencies were calculated as a percent difference between test sample runs and the control average using the following equation:

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

Where: C = Average of control values.
T = Count total for test material.

This test procedure produces a more severe challenge to most filtration materials than would be expected in normal use. The purpose of this procedure is not to optimize the filtration efficiency, but to consistently measure as accurately as possible the differences between materials, or differences in the same material over time, thereby alerting the manufacturer to significant trends or changes which can then be dealt with promptly.

Several quality control steps have been taken to insure and monitor our own ability to consistently perform the bacterial filtration efficiency procedure:

1 - The test control average, determined from control runs where no filter medium is in the airstream, must be maintained at 2200 ± 500 CFU for the test to be valid, unless the sponsor approves another control average.

2 - We include at least one reference material with every 5-10 samples tested. Statistical evaluation of these reference material data are recorded on control charts. The reference material must be within the upper and lower control limits (±3 standard deviations) established for the test.

3 - The test sample results are statistically analyzed to alert us to unusual variations which may indicate a need for retesting before data are reported.

The ΔP test simply measured the differential air pressure on either side of the test sample using an incline or "U" tube manometer. Testing was conducted at a flow rate of 8 Lpm (volumetric). This value represents a corrected flow rate, which compensates for temperature and altitude differences. In the past, Nelson Laboratories conducted ΔP testing using a flow rate which was based on a water calibration procedure. To improve the accuracy and reproducibility of the ΔP test, the 8 Lpm flow rate used in testing is now based on a calibrated value using a BIOS DryCal® DC-2M Primary Flow Meter. This flow meter is a primary calibration standard and gives a higher level of confidence with regards to its accuracy. It is expected that ΔP values obtained using this volumetric flow rate will yield results approximately 10% higher than had previously been reported. The ΔP values were reported in mm water/cm² of test area and calculated using the following equation:

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$$DELTA\ P\ (\Delta p) = \frac{\bar{M}}{TEST\ AREA}$$

Where: $\bar{M}$ = Average mm of water of the test replicates.

The sample holder used in the ΔP test has a test area of 4.9 cm^2.

At least one reference material is included with each set of test samples. The differential pressure values for the reference material are also recorded on control charts. The individual differential pressure values must be within the upper and lower control limits (±3 standard deviations) for the test.

STATEMENT OF UNCERTAINTY:

BFE Procedure: Due to the large number of data points available for the standard reference material used in the BFE test, the Type B uncertainty factors have been determined to be incorporated into the Type A uncertainty.

Statistical analysis of the BFE data resulted in the following:

Bacterial Filtration Efficiency (BFE) Mean = 99.3 %
Standard Deviation = 0.29%

The combined standard uncertainty for the BFE test is 0.027% Bacterial Filtration Efficiency and the expanded uncertainty at a 95% confidence level is 0.055% Bacterial Filtration Efficiency.

It should be noted that the statistical analysis was conducted on data from Nelson Laboratories' standard reference material with a mean of 99.3%. It is expected that materials submitted for BFE testing which have a BFE lower than 99.3% would have a combined uncertainty and an expanded uncertainty greater than the uncertainty values reported here. Conversely, test materials with BFE values greater than 99.3% would be expected to yield a combined uncertainty and an expanded uncertainty less than the uncertainty values reported here.

ΔP Procedure: Due to the large number of data points available for the standard reference material used in the Differential Pressure (Delta P) test, the Type B uncertainty factors have been determined to be incorporated into the Type A uncertainty.

TEST RAPPORT

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Lab Number 246885

BFE/ΔP Tests
Page 6

A statistical analysis of the Delta P data resulted in the following:

Delta P Mean = 2.0
Standard Deviation = 0.06

The combined uncertainty for the Delta P test is 0.0056 (0.6%) and the expanded uncertainty value at 95% Confidence Level is 0.011 (1.1%).

It should be noted that the statistical analysis was conducted on data from Nelson Laboratories' standard reference material with a mean of 2.0. It is expected that materials submitted for Delta P testing which have a Delta P higher than 2.0 would have a combined uncertainty and an expanded uncertainty greater than the uncertainty values reported here. Conversely, test materials with Delta P values of less than 2.0 would be expected to yield a combined uncertainty and an expanded uncertainty less than the uncertainty values reported here.

Test samples were not collected by the laboratory and therefore the representative nature of the samples is not included in the uncertainty assessment.

Stacey Cushing

Stacey Cushing, B.S.
Associate Study Director

Brandy Giles

Brandy Giles, B.S.
Study Director

10 Oct 2003
Study Completion Date

ejb

扫描全能王 创建

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BFE/ΔP Tests
Page 7

TABLE 1. Results

UNIT NUMBER	SAMPLE IDENTIFICATION	ΔP (mm H_2O/cm^2)	PERCENT BFE
1	Non Woven Face Masks - 1	2.1	94.0%
2	Non Woven Face Masks - 2	2.2	96.3%
3	Non Woven Face Masks - 3	2.0	97.2%
4	Non Woven Face Masks - 4	2.1	97.1%
5	Non Woven Face Masks - 5	2.0	96.1%

CONTROL AVERAGE: 1983 CFU

MEAN PARTICLE SIZE: 3.1 μm

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Lab Number 246885

BFE/ΔP Tests
Page 8

REFERENCES:

MIL-M-36954C. 1975. Headquarters, Defense Personnel Support Center, Philadelphia, PA.

ASTM F2101-01. 2001. Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*. American Society for Testing and Materials, West Conshohocken, PA.

ASTM F2100-01. 2001. Standard Specification for Performance of Materials Used in Medical Face Masks. American Society for Testing and Materials, West Conshohocken, PA.

Andersen 2000 Inc. 1976. Viable (Microbial) Particle Sizing Samplers Operating Manual. Andersen 2000 Inc., Atlanta, GA.

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Lab Number 246885

BFE/ΔP Tests
Page 9

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CONFORMITEITSVERKLARING

DoC

HANDELSONDERNEMING IVA

01/04/2020

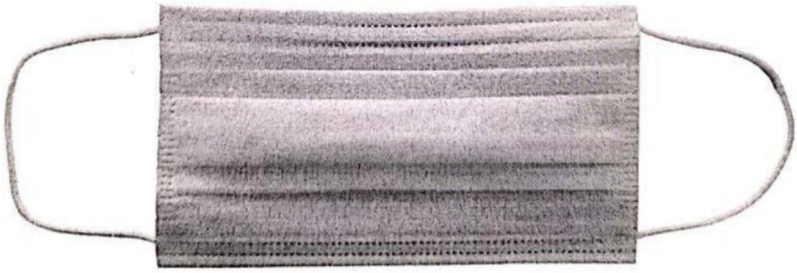
CE

DECLARATION OF CONFORMITY
CONFORMITEITSVERKLARING
DÉCLARATION DE CONFORMITÉ
KONFORMITÄTSERKLÄRUNG

IVA Handelsonderneming B.V.
Barwoutswaarder 13 C
3449HE Woerden
info@masklogic.nl
+ 31 348 688 088

Verklaart dat onder haar volledige verantwoording het volgende product:
Declares under its sole responsability that the following product:
Déclare que sous sa responsabilité le produit suivant:
Erklärt daß eigenverantwortlich das nachstehende Produkt:

Disposable medical mask
21.5*9.5 - 18*9.5 - 17.5*9.5 - 16.5*9.5 - 14.5*9 - 12.5*9



Volledig voldoet aan de essentiële voorwaarden van de volgende EU-regelgevingen of andere nationale documenten:
Fully complies with the essential requirements of the relevant EU directives and other normative documents:
Répond entièrement aux critères essentiels des réglémentations de l'UE ou d'autres documents internationaux:
Vollständig den grundlegenden Voraussetzungen der nachstehenden EU Reglung oder anderen nationalen Dokumenten entspricht:

CONFORMITEITSVERKLARING

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01/04/2020

Directive/regulation	Standard detail and/or measurement reference
Medical Devices Directive 93/42/EEC Annex VII	EN 14683 Class I (no sterile) Test Report identified with the no. BTS-20189M.

De aangemelde instantie Ente Certificazione Macchine, Italie, www.entecerma.it (Notified Body number: 1282) heeft op basis van een door Nelson Laboratories, Salt Lake City, USA, www.nelsonlabs.com uitgevoerde controle op 12 maart 2020 en het volgende certificaat verstrekt:

No. 4M200312.TSSU054

Dit is geldig tot **11 Maart 2025**

Ondertekend voor en namens de importeur, IVA Handelsonderneming,
Signed for and on behalf of the importer, IVA Handelsonderneming,

Ad Oude Bos
Algemeen Directeur/Managing Director