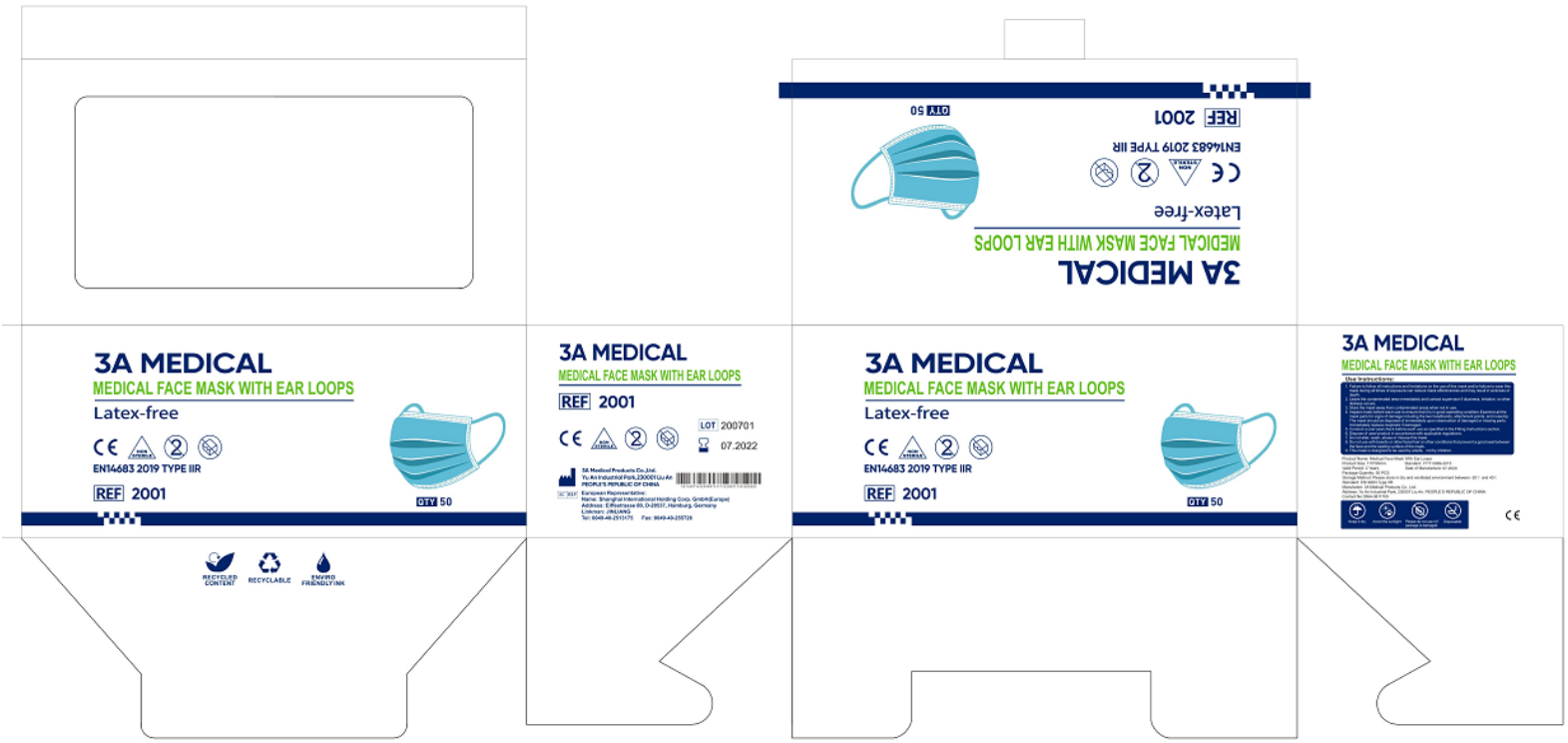
Dokumentation TYP IIR 3A Medical

TYP IIR
3A Medical

Klassenkennzeichnung	3 – lagige MNS TYP IIR
Typenkennzeichnung (Modell)	REF 2001
Zertifizierung	EN 14683:2019 TYP IIR Konformitätskennzeichen entsprechend der Regulation (MDD 93/42
Hersteller	3A Medical Products Co. Ltd. Yu An Industrial Park, 230001 Liu An PEOPLE´S REPUBLIC OF CHINA
Zugelassener Vertreter der EU	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg
Haltbarkeit	2 Jahre bei Lagerung in feuchtigkeitsbeständigem, regenfreiem und belüftetem Raum.
Verpackung	50 Masken im Beutel in einer Box 40 Boxen im Karton = 2.000 Masken / Karton
Maße	Box (19cm*10cm*8cm) Karton (52cm*39,5cm*34cm)
Produktspezifikationen	3-Lagig Ohrschlaufen Latexfrei Material: SPP / Melt Blown Farbe: weiß / blau Einmalgebrauch
Produktabmessungen	17,5cm*9,5cm


3A MEDICAL
MEDICAL FACE MASK WITH EAR LOOPS
Latex-free
EN14683 2019 TYPE IIR
REF 2001
QTY 50
RECYCLED CONTENT
RECYCLABLE
ENVIRO FRIENDLY INK
3A MEDICAL
MEDICAL FACE MASK WITH EAR LOOPS
REF 2001
LOT 200701
07.2022
3A MEDICAL
MEDICAL FACE MASK WITH EAR LOOPS
Latex-free
EN14683 2019 TYPE IIR
REF 2001
QTY 50
3A MEDICAL
MEDICAL FACE MASK WITH EAR LOOPS
QTY 50
REF 2001
EN14683 2019 TYPE IIR
Latex-free
3A MEDICAL
MEDICAL FACE MASK WITH EAR LOOPS

3A MEDICAL

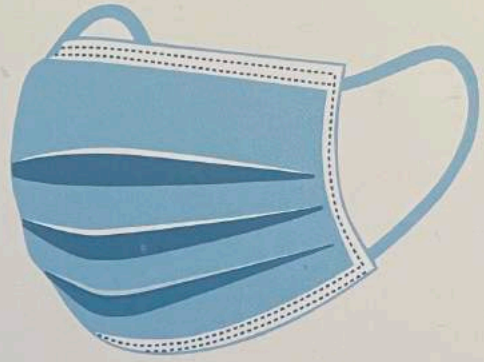
MEDICAL FACE MASK WITH EAR LOOPS

Latex-free

CE NON STERILE 2

EN14683 : 2019 TYPE IIR

REF 2001



QTY 50

3A MEDICAL

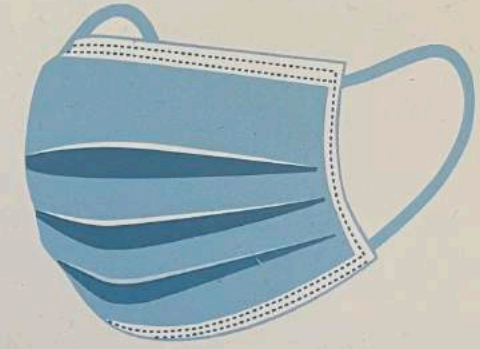
MEDICAL FACE MASK WITH EAR LOOPS

Latex-free

CE NON STERILE 2

EN14683 : 2019 TYPE IIR

REF 2001



QTY 50


3A MEDICAL
MEDICAL FACE MASK WITH EAR LOOPS
REF 2001
LOT 200803
NON STERILE
08.2022
3A Medical Products Co.,Ltd.
Yu An Industrial Park,230001 Liu An
PEOPLE'S PEPUBLIC OF CHINA
(01)6971432939975(17)220831(10)200803
EC REP
European Representative:
Name: Shanghai International Holding Corp. GmbH(Europe)
Address: Eiffestrasse 80, D-20537, Hamburg, Germany
Linkman: JINLIANG
Tel: 0049-40-2513175 Fax: 0049-40-255726

Use Instructions:

GB No mask completely removes the risk of contamination from blood or body fluids

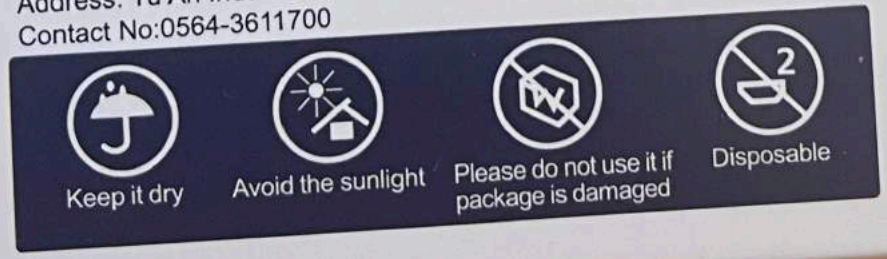
DE Keine Maske beseitigt das Risiko einer Kontamination durch Blut oder Körperflüssigkeiten vollständig

FR Aucun masque ne supprime complètement le risque de contamination par le sang ou les fluides corporels

ES Ninguna máscara elimina por completo el riesgo de contaminación de sangre o fluidos corporales

IT Nessuna maschera rimuove completamente il rischio di contaminazione da sangue o fluidi corporei

Product Name: Medical Face Mask With Ear Loops
Product Size: 175*95mm
Standard: YY/T 0969-2013
Valid Period: 2 Years
Date of Manufacture: 08.2020
Package Quantity: 50 PCS
Storage Method: Please store in dry and ventilated environment between -20℃ and 40℃
Standard: EN14683:2019 Type IIR
Manufacter: 3A Medical Products Co., Ltd.
Address: Yu An Industrial Park, 230001 Liu An. PEOPLE'S REPUBLIC OF CHINA
Contact No:0564-3611700



CE


RECYCLED CONTENT
RECYCLABLE
ENVIRO FRIENDLY INK

Konformitätserklärung des Herstellers

安徽富美医疗科技有限公司
3A Medical Products Co., Ltd.
地址：安徽省六安市裕安区
Add: Yu An Industrial Park, Liu An City, P.R. China

Declaration of Conformity

Manufacturer: 3A Medical Products Co., Ltd
Address: Yu An Industrial Park, 237100, Liu An, PEOPLE'S REPUBLIC OF CHINA

European Representative:

Name: Shanghai International Holding Corp. GmbH(Hamburg)

Address: Eiffestrasse 80, 20537, Hamburg, Germany

Product name： Medical face mask
Classification: Class 1 Rule 1of Annex IX of MDD 93/42/EEC)
Type： Type IIR
Rule: According to Rule I Annex VII

We here with declare that above mentioned products meet the requirement of the (MDD 93/42/EEC) Medical device directive and the following harmonized standards:

EN14683:2019
ENISO 15223-1:2016
ENISO10993-1:2009/AC: 2010
ENISO10993-10:2013
ENISO 14971:2012
ENISO1041:2008A1:2013
ENISO10993-5:2009

The Medical face mask meets the requirement of EN14683:2019

Signature Billy Zhang 2020.4.17
Name: Billy Zhang
Position: Management Representative
Place： Liu An City
Date: 2020-04-17

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

3A Medical Products Co., Ltd
Yu An Industrial Park
Yu An district
Liu An
Anhui
237100
China

安徽富美医疗科技有限公司
中国
安徽省
六安市
裕安区
城南工业园
邮编：237100

Holds Certificate No: **MD 731336**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture and Distribution of following medical devices: sterile Surgical Mask, sterile Medical Mask, sterile Surgical Gown, sterile Medical Coverall, sterile Surgical Drape, sterile Surgical Pack, and non-sterile Isolation Gown, non-sterile Shoe Cover, non-sterile Pillow Cover, non-sterile Sleeve Cover, non-sterile Non-woven Swabs, non-sterile Surgical Cap, non-sterile Head Cover, non-sterile Fluorocover, non-sterile Scrub sult, non-sterile Bed Cover.
以下产品的生产和销售：无菌的医用外科口罩、一次性使用医用口罩、一次性使用手术衣、医用一次性防护服、一次性使用手术铺单、一次性使用无菌手术包；非无菌的隔离衣、医用隔离鞋套鞋套、枕套、袖套、无纺布纱布、卫生帽手术帽、医用帽、机头罩、消毒服、床罩。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-09-21
Latest Revision Date: 2020-09-21

Effective Date: 2020-09-21
Expiry Date: 2023-09-20

...making excellence a habit.™

DIMDI Eintragung

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304117

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA05**		
	Bezeichnung / Name **Behörde für Gesundheit und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20539**
	Straße, Haus-Nr. / Street, house no. **Billstraße 80**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@bgv.hamburg.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority		Registriernummer / Registration number
	Typ der Anzeige / Notification type S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG £ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV £ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304117

Anzeigender / Reporting organisation (person)			
	Code **DE/0000040627**		
	Bezeichnung / Name **Shanghai International Holding Corporation GmbH (Europe)**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestrasse 80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **3A Medical Products Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Liu An,**		Postleitzahl / Postal code **230001**
	Straße, Haus-Nr. / Street, house no. **Yu An Industrial Park,**		
	Telefon / Phone **+86-564-3611700**		Telefax / Fax **+86-564-3611700**
	E-Mail / E-mail **guweilin@3a-medical.cn**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Liang Jin**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestr.80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304117

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	£ Erstanzeige / Initial notification S Änderungsanzeige / Notification of change		

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304117

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class S I £ I - steril / sterile £ I - mit Messfunktion / with measuring function £ I - steril und mit Messfunktion / sterile and with measuring function £ IIa £ IIb £ III £ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 £ Aktives implantierbares Medizinprodukt / Active implantable medical device £ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **3A**
	Produktbezeichnung / Name of device **Medical face mask**
	Nomenklaturcode / Nomenclature code **12-447**
	Nomenklaturbezeichnung / Nomenclature term **Maske**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description **Medical face mask is intend to be used for hygiene care which the wearer under general medical environment where there is no risk of bodily fluids splash.**

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304117

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	£ Semikritische Medizinprodukte / Semicritical medical devices £ Gruppe A / Group A £ Gruppe B / Group B
	£ Kritische Medizinprodukte / Critical medical devices £ Gruppe A / Group A £ Gruppe B / Group B £ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures £ Dampfsterilisation / Steam sterilisation £ Gassterilisation / Gas sterilisation £ Strahlensterilisation / Radiation sterilisation £ andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Hamburg**

Datum
Date **2020-04-30**

Name **Liang Jin**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

CERTIFICATE OF NOTIFICATION

This is to certify that, according to European Council Directive 93/42/EEC, Shanghai International Holding Corp, GmbH (Europe), performed all notification duties and responsibilities as the European authorized Representative:

MANUFACTURER: 3A Medical Products Pty Ltd

Address: Yu An Industrial Park, 230001, Liu An, CN

The manufacturer has provided Shanghai International Holding Corp, GmbH (Europe), with all the appropriate declaration according to the European Council Directive 93/42 EEC including the EC Declaration of Conformity confirming that its medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 93/42/EEC.

Devices: Medical Face Mask

Classification: I

Model: 17.5(±5%)cm*9.5(±5%)cm,14.5(±5%)cm*9.5(±5%)cm

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 93/42/EEC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Germany. The Germany Competent Authority is notified of the manufacture's device and has allocated registration.

EXECUTIVE DIRECTOR

Shine

Test Report

3A Medical Products Co. Ltd, Yu An Industrial Park, 230001 Liu An. PR China

Your notice of	Your reference	Date
17-03-2020		03-04-2020

Analysis Report 20.01605.03

Required tests :

EN 14683 (2019) + AC (2019)	**EN 14683 - annex B (2019) + AC (2019)**	**Bacterial filtration efficiency**
EN 14683 (2019) + AC (2019)	**ISO 22609 (2004)**	**Medical face masks - Splash Test**
EN 14683 (2019) + AC (2019)	**EN 14683 - annex C (2019) + AC (2019)**	**Medical face masks - Breathability (differential pressure)**
EN 14683 (2019) + AC (2019)	**EN 14683 - §5.2.5 (2019) AC (2019)**	**Microbial cleanliness on masks**

Identification number	Information given by the client	Date of receipt
T2006058	REF 2001 Lot 202001202	17-03-2020

Sylvie Niessen
Order responsible

The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

ISO 17025 BELAC 056-TEST

CENTEXBEL • textile competence centre • www.centexbel.be • www.vkc.be
GENT • Technologiepark 70 • BE-9052 Zwijnaarde, Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be
GRÂCE-HOLLOGNE • Rue du Travail 5 • BE-4460 Grâce-Hollogne, Belgium • phone +32 4 296 82 00 • g-h@centexbel.be
KORTRIJK • Etienne Sabbelaan 49 • BE-8500 Kortrijk, Belgium • phone +32 56 29 27 00 • fax +32 56 29 27 01 • info@vkc.be
VAT BE 0459.218.289 • IBAN BE44 2100 4729 6545 • BIC GEBABEBB

Reference: **T2006058 - REF 2001**
Lot 202001202

Bacterial filtration efficiency

Date of ending the test	25-03-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	3 layers/ 18gsm SPP white/ 25gsm/meltex/ 22gsm SPP blue
Number of tested masks :	5
BFE Area tested :	± 49 cm²
Masks conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	1700 - 3000 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge

Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} \; X \; 100$$

With C = mean of the total plate counts for the positive control runs
T = total count for the tested mask

# Mask	B (%)
1	99.9
2	99.2
3	99.8
4	99.9
5	99.8

Mean particle size of the bacterial challenge aerosol : 2.9 µm

Controls

Mean positive controls 2636 CFU
Negative control < 1 CFU

Reference: **T2006058 - REF 2001**
Lot 202001202

Medical face masks - Splash Test

Date of ending the test	26-03-2020
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	3 layers/ 18gsm SPP white/ 25gsm/meltex/ 22gsm SPP blue
Number of tested masks :	32
Blood surface tension	42 ± 2 dynes/cm
Volume of the delivered blood	2 ml
Distance "canula-mask"	30 ± 1 cm
Side of the mask "impacted"	Outer side
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Results

Blood pressure tested **16.0 kPa**

Controls

Blood visualisation on the mask	OK
Calibration procedure	OK
Control of the blood volume delivered (2 ml)	
- before the test :	OK
- after 16 masks :	OK
- after 32 masks :	OK

Results obtained on the set of masks

# Mask	Results : pass / fail
1	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

Summary P = 16.0 kPa

Number of "Pass" masks	Number of "Fail" masks
32	0

Pass = no blood detected on the observed side
Fail = blood detected on the observed side

In agreement with the customer the number of tested mask has been determined based on a single sampling plan providing an AQL of 4 % (acceptable quality limit).

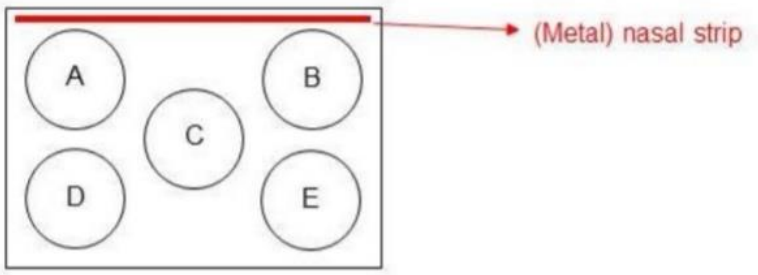
If 29 masks or more over 32 obtain a "Pass" result the 4% AQL is reached.

Reference: **T2006058 - REF 2001**
Lot 202001202

Medical face masks - Breathability (differential pressure)

Date of ending the test	24-03-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	3 layers/ 18gsm SPP white/ 25gsm/meltex/ 22gsm SPP blue
Number of tested masks :	5
Number of areas per mask	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm²
Flow rate :	8 l/min.
Direction of the air flow :	From the inside of the mask to the outside
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask



Results **Δ P**

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	52.6	23.0	52.6	35.2	40.3
Area B	51.1	30.6	59.1	39.7	39.7
Area C	53.0	34.8	45.4	43.4	38.3
Area D	46.7	35.7	48.1	44.2	41.4
Area E	44.2	29.7	39.5	39.7	41.4
Average ΔP (Pa/cm²)	**49.5**	**30.8**	**48.9**	**40.4**	**40.2**

Reference: **T2006058 - REF 2001**
Lot 202001202

Microbial cleanliness on masks

Date of ending the test	30-03-2020
Standard used	EN 14683 - §5.2.5 (2019) AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks	5
Extraction liquid	Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l
Extraction volume	300 ml
Extraction time	5 min.
Counting technique	Membrane filtration
Filtration volume	100 ml
Culture media	TSA (Tryptic Soy Agar) SDA (Sabouraud Dextrose Agar with chloramphenicol)
Incubation conditions	3 days at 30°C (TSA) 7 days at 20-25°C (SDA)

Results

# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		Aerobic microbial count (bacteria)	*Fungi count (SDA)*	*Σ CFU/mask*	*Σ CFU/g*
1	4.25	33	<3	< 36	< 9
2	4.22	3	<3	< 6	< 2
3	4.33	3	<3	< 6	< 2
4	4.35	36	<3	< 39	< 9
5	4.37	3	<3	< 6	< 2