

3A Medical Face Mask

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1. Basic Information

Brand: 3A

Model: Latex-free Medical Face Mask

Product Code: 2001

CE standard: EN 14683:2019

Classifications: Type IIR (Non-Sterile)

Material: SPP, Melt-blown fabric

Design: Earloop

Size: 17.5cm*9.5cm

Expiration date: 2 years

Packaging:

50pcs per box, 40 boxes per carton, 2000 pcs per carton

Box Size: 19*10*8cm

Carton Size: 52*39.5*34cm

Gross Weight: 9.5 kg

2. Pictures





3A MEDICAL 合格证

(CERTIFICATE OF QUALIFICATION)

产品名称：一次性使用医用口罩	产品品牌：3A Medical
Product: Medical Face Mask With Ear Loops	Brand Name: 3A Medical
产品型号：平面A型	产品代号：2001
Product Type: Plat type A	Product Code: 2001
产品规格：17.5*9.5cm	材料成份：68%SPP无纺布+32%熔喷
Product dimension: 17.5*9.5	Material Ingredient: 68%SPP+32% Melt-blow
生产批号：200701	执行标准：YY/T 0969-2013
Batch Number: 200701	Standard: YY/T 0969-2013
包装数量：50只/盒	生产日期：07. 2020
Package Quantity: 50 pieces/pack	Date of Manufacture: 07. 2020
检验日期：07. 2020	
Inspection Date: 07. 2020	

有效期：储存温度-20°C-40°C，储存湿度≤80%，避光干燥的室内环境下，有效期2年。
 Expiry Date: The storage temperature is -20°C-40°C, the storage humidity is ≤80%, and it is valid for 2 years in dry indoor environment.

适用范围：用于佩戴者在不存在体液和喷溅风险的普通医疗环境下的卫生护理。
 Scope Of Application: Used for health care of the wearer in the general medical environment without the risk of body fluids and splashes.

产品注册证编号：皖械注准20202140040
 Product Registration Certificate No: Anhui machinery No 20202140040
 医疗器械生产许可证号：皖食药监械生产许20180032号
 Medical Device production license No: Anhui Food and Drug Administration production license No. 20180032

生产厂商：安徽富美医疗科技有限公司
 Manufacturer: 3A Medical Products Co., Ltd
 电话：0564-3611700
 Tel: 0564-3611700
 生产地址：安徽省六安市裕安区城南工业园区工业路1号
 Address: Yu An Industrial Park 230001 Liu AN, People' s Republic of China

3. Form for Medical Device Registration

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	Land / Federal state
Deutschland	Hamburg
Ort / City	Postleitzahl / Postal code
Hamburg	20539
Straße, Haus-Nr. / Street, house no.	
Billstraße 80	
Telefon / Phone	Telefax / Fax
+49-40-428280	+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 E Änderungsanzeige / Notification of change E 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 E Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative E Einführer / Importer E 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 E 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 E 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	

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	

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

Angela Q. GmbH

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
Klasse / Class	
S I	
E I - steril / sterile	
E I - mit Messfunktion / with measuring function	
E I - steril und mit Messfunktion / sterile and with measuring function	
E IIa	
E IIb	
E III	
E 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	
E Aktives implantierbares Medizinprodukt / Active implantable medical device	
E 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)	E 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.

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	E. Semikritische Medizinprodukte / Semicritical medical devices E. Gruppe A / Group A E. Gruppe B / Group B
	E. Kritische Medizinprodukte / Critical medical devices E. Gruppe A / Group A E. Gruppe B / Group B E. Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures E. Dampfsterilisation / Steam sterilisation E. Gassterilisation / Gas sterilisation E. Strahlensterilisation / Radiation sterilisation E. 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	<u>Hamburg</u>	Datum Date	<u>2020-04-30</u>
		Name	<u>Liang Jin</u>
			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

4. Declaration of Conformity

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 I Rule I of 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

ENISO14971:2012

ENISO15223-1:2016

ENISO1041:2008A1:2013

ENISO10993-1:2009/AC:2010

ENISO10993-5:2009

ENISO10993-10:2013

The medical face mask meet the requirement of EN14683:2019.

Signature Billy Zhang 2020/07/17

Name: Billy Zhang

Position: Management Representative

Place: Liu An City

Date: 2020-07-17



5. Full Analysis Report



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

Your notice of
17-03-2020

Your reference

Date
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

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INRICHTING ERKEND BIJZONDERING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947



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INRICHTING ERKENDBIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947

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 cm ²
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 :	<i>Staphylococcus aureus</i> 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 (%)

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

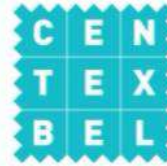
With C = mean of the total plate counts for the positive control runs
 T = total count for the tested mask

# 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

INRICHTING ERKENDE TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947



INRICHTING ERKEVD 03 TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947

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).

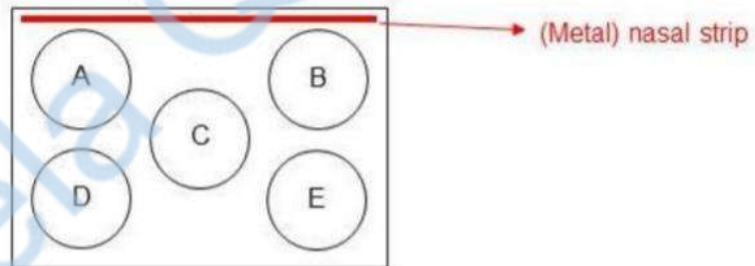
If 29 masks or more over 32 obtain a "Pass" result the 4% AQL is reached.

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 cm ²
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 ΔP

	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	
		<i>Aerobic microbial count (bacteria)</i>	<i>Fungi count (SDA)</i>	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