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
Product:Medical Face Mask With Ear Loops

产品品牌：3A Medical
Brand Name: 3A Medical

产品型号：平面A型
Product Type: Plat type A

产品代号：2001
Product Code: 2001

产品规格：17.5*9.5cm
Product dimension: 17.5*9.5

材料成份：68%SPP无纺布+32%熔喷
Material Ingredient: 68%SPP +32% Melt-blow

生产批号：200701
Batch Number:200701

执行标准：YY/T 0969-2013
Standard: YY/T 0969-2013

包装数量：50只/盒
Package Quantity: 50 pieces/pack

生产日期：07. 2020
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 **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		

- 1 -

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 $ 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

4. Declaration of Conformity

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

安徽富美医疗科技有限公司 3A Medical Products Co., Ltd

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

5. Full Analysis Report

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

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

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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
ilac-MRA
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INRICHTING ERKEND BIJ 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 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

Performed in the microbiological lab under the responsibility of Yvette Rogister

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

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

Performed in the microbiological lab under the responsibility of Yvette Rogister

INRICHTING ERKEND BIJ 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

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

Performed in the microbiological lab under the responsibility of Yvette Rogister

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-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

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

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.

Performed in the microbiological lab under the responsibility of Yvette Rogister

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

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

Performed in the microbiological lab under the responsibility of Yvette Rogister

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

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**

Performed in the microbiological lab under the responsibility of Yvette Rogister

INRICHTING ERKEND BIJ 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

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

Performed under accreditation in the microbiological lab under the responsibility of Yvette Rogister