TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60127[redacted]

Report No.: 150447[redacted]

Manufacturer: [redacted] Medical Instrument
[redacted] Jiaxian
[redacted]
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60114594 0001

Expiry Date: 2021-10-22

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-07-06

Date: 2018-07-06

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 601[redacted]
Report No.: 150447[redacted]

Manufacturer: [redacted] Medical Instrument
[redacted] Road, Jiaxian
467[redacted]
China

Products:
Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use (Sterile Infusion Sets with Needles, Sterile Bag Type Infusion Sets with Needles, Disposable Infusion Sets with Precision Filters, Disposable Precise Filter Light-resistant Infusion Sets, Disposable Flow Trimming Precision Filter Infusion Sets With Needles, Disposable Fluid Automatic Stopped Infusion Sets With Needles), Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Disposable Blood Transfusion Sets, Disposable I.V. Catheters, Disposable Venous Blood Collection Needles, Disposable Nasal Oxygen Cannulas, Sterile Insulin Syringes for Single Use, Sterile Retraction Type Safety Syringes for Single Use, Disposable Safety Intravenous Catheters, Tracheal Tubes for Single Use, Breathing Tubes, Disposable Oxygen Masks, Disposable Stomach Tube Kits, Disposable Endotracheal Intubation Kits, Medical Laryngeal Masks, Anesthesia Masks, Heat and Moisture Exchangers, Syringes for Fixed-Dose immunization with Retractable Needle, Disposable Heparin Caps, Disposable Urethral Catheter Kits

Notified Body

Date: 2018-07-06

X. Ren

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 601[redacted]
Report No.: 150447[redacted]

Manufacturer: [redacted]dical Instrument
Ea[redacted]Road, Jiaxian
[redacted]
Chi[redacted]

Aspects of manufacture concerned with securing and maintaining sterile conditions:
Disposable Drainage Bags, Disposable Medical Pads, Medical Caps, Surgical Masks, Disposable Suction Catheters, Disposable Spatula, Disposable Vaginal Dilators, Wound Plasters, Drainage Tubes for Single Use, Sterile Medical Cotton Balls, Sterile Medical Sheets, Sterile Cotton Swabs, Examination Gloves, Disposable Dressing Kits, Medical Absorbent Gauze Pieces, Medical Absorbent Gauze Pads, Disposable Medical Films, Positive Pressure Needle-Free Infusion Connectors, Medical Use Cotton Rolls, Medical Gauze Bandages, Medical Elastic Bandages, Oropharyngeal Airways, Disposable Sterile Dispensing Syringes, Disposable Delivery Kits, Medical Masks, Protectors for Transfusion Joint, Disposable Oral Irrigation Tubes

Notified Body

Date: 2018-07-06

X. Ren

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

[redacted]CO.,LTD
AD[redacted]HENAN,CHINA

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

[redacted]nstrument
Jiaxian
[redacted]ity
[redacted]enan
[redacted]hina

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-03-24
Certificate Registration No.:	SX 60141[redacted]0001
An audit was performed. Report No.:	1504477[redacted]
This Certificate is valid until:	2023-01-31

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-03-24

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: SX 601[redacted]
Report No.: 150447[redacted]

Organization: [redacted] Medical Instrument
[redacted]han Road, Jiaxian
[redacted]ity
[redacted]n
P[redacted]

Scope:

Products:
Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use (Sterile Infusion Sets with Needles, Sterile Bag Type Infusion Sets with Needles, Disposable Infusion Sets with Precision Filters, Disposable Precise Filter Light-resistant Infusion Sets, Disposable Flow Trimming Precision Filter Infusion Sets With Needles, Disposable Fluid Automatic Stopped Infusion Sets With Needles), Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Disposable Blood Transfusion Sets, Disposable I.V. Catheters, Disposable Venous Blood Collection Needles, Disposable Nasal Oxygen Cannulas, Sterile Insulin Syringes for Single Use, Sterile Retraction Type Safety Syringes for Single Use, Disposable Safety Intravenous Catheters, Tracheal Tubes for Single Use, Breathing Tubes, Disposable Oxygen Masks, Disposable Stomach Tube Kits, Disposable Endotracheal Intubation Kits, Medical Laryngeal Masks, Anesthesia Masks, Heat and Moisture Exchangers

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-03-24

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜVRheinland

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: SX 601[redacted]
Report No.: 150447[redacted]

Organization: [redacted] Medical Instrument
[redacted] Road, Jiaxian
[redacted]ian
[redacted] China

Scope:

Products:
Syringes for Fixed-Dose immunization with Retractable Needles, Disposable Heparin Caps, Disposable Urethral Catheter Kits, Disposable Drainage Bags, Disposable Medical Pads, Medical Caps, Surgical Masks, Disposable Suction Catheters, Disposable Spatula, Disposable Vaginal Dilators, Wound Plasters, Drainage Tubes for Single Use, Sterile Medical Cotton Balls, Sterile Medical Sheets, Sterile Cotton Swabs, Examination Gloves, Disposable Dressing Kits, Medical Absorbent Gauze Pieces, Medical Absorbent Gauze Pads, Disposable Medical Films, Positive Pressure Needle-Free Infusion Connectors, Medical Use Cotton Rolls, Medical Gauze Bandages, Medical Elastic Bandages, Oropharyngeal Airways, Disposable Sterile Dispensing Syringes, Disposable Delivery Kits, Medical Masks, Protectors for Transfusion Joint, Disposable Oral Irrigation Tubes

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-03-24

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Fuxiu Sheng

[redacted]D
ADD.[redacted]INA
WWW.S[redacted]CAL.COM ;

Test Report No.: 72165[redacted]
Report Date: 17 April 2[redacted]

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]**dical Instrument Co., Ltd.**
CLIENT ADDRESS	[redacted]Pingdingshan City,Henan,China
TEST PERIOD	28-Mar-2020~06-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo Liu
(Bella Xu)	(Leo Liu)
Report Drafter	Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report No.: 7216[redacted]5
Report Date: 17 April 2020

TEST REPORT

Sample Description	:	Medical Masks
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	200318
Specification	:	/
Size	:	17.5cmX9.5cm
Type of Mask	:	Type IIR
Brand Name	:	/

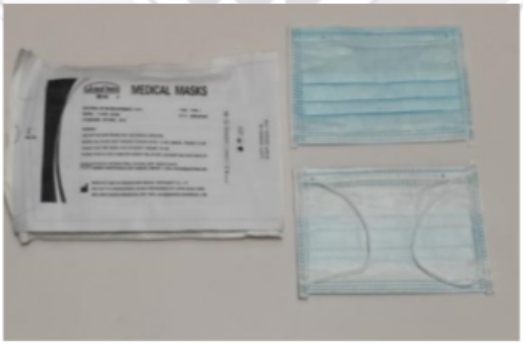
Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

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

Photo of Samples



Test Report No.: 72165[redacted]
Report Date: 17 April 2020

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.6% Specimen 2#: 99.2% Specimen 3#: 99.4% Specimen 4#: 99.4% Specimen 5#: 99.3%
2	Differential Pressure Test	27.1 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 3 CFU/g Specimen 3#: 1 CFU/g Specimen 4#: 1 CFU/g Specimen 5#: 2 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 : Medical Masks
Specification : /
Lot Number : 200318
Sample Receiving Date : 2020-03-28

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)℃ 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: 77cm²).
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)℃ 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:

$$BFE=(C-T)/C\times100$$

T is the total plate count for the test specimen.

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

Test Report No.: 721653275
Report Date: 17 April 2020

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	16	34	0	0	0	0	0	0
2	45	31	0	0	0	0	0	0
3	75	99	0	0	1	1	0	0
4	218	279	0	0	1	0	0	0
5	1125	1288	0	4	5	8	6	11
6	447	359	0	5	10	4	7	4
Total (*T*), CFU	1926	2090	<1	9	17	13	13	15
Average (*C*), CFU	$2.0x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.6	99.2	99.4	99.4	99.3
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.							