Prüfbericht-Nr.: *Test Report No.*:	**60377885 001**	**Auftrags-Nr.** *Order No.*:	**168264966**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.*:	N/A	**Auftragsdatum:** *Order date*:	May 14, 2020	
Auftraggeber: *Client*:	**Henan Siyuan Medical Equipment Co., Ltd** Industrial cluster, Huanglou Road, Shaolin Avenue, Dengfeng City, Zhengzhou City, Henan Province, China, 452470			
Prüfgegenstand: *Test item*:	Single-use medical face mask (non-sterile)			
Bezeichnung / Typ-Nr.: *Identification / Type No.*:	Flat Type(blue)			
Auftrags-Inhalt: *Order content*:	Type test			
Prüfgrundlage: *Test specification*:	EN 14683:2019+AC:2019 except for clause 5.2.6			

Wareneingangsdatum: *Date of receipt*:	May 18, 2020
Prüfmuster-Nr.: *Test sample No.*:	20042801
Prüfzeitraum: *Testing period*:	May 19, 2020 to Jun. 04, 2020
Ort der Prüfung: *Place of testing*:	See page 3
Prüflaboratorium: *Testing laboratory*:	TÜV Rheinland (Shenzhen) Co., Ltd.
Prüfergebnis*: *Test result**:	Pass

See Attachment: Photo documentation for details.

geprüft von / *tested by*:

Javen Ke

Jun. 12, 2020 Javen Ke/Assistant Project Engineer

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by*:

Angela C

Jun. 12, 2020 Angela Chen / Department Manager

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other*:

- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (5 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m. test specification(s)		*F(ail) = failed a.m. test specification(s)*	*N/A = not applicable*	*N/T = not tested*

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	**60377885 001**
Date of issue ..... :	**See cover page**
Total number of pages ..... :	**See cover page**
Testing Laboratory ..... :	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address ..... :	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name ..... :	**Henan Siyuan Medical Equipment Co., Ltd**
Address ..... :	Industrial cluster, Huanglou Road, Shaolin Avenue, Dengfeng City, Zhengzhou City, Henan Province, China, 452470
Test specification:	
Standard ..... :	EN 14683:2019+AC:2019
Test procedure ..... :	Type test
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019_A
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-03
Test item description ..... :	Single-use medical face mask (non-sterile)
Trade Mark ..... :	GUANJOY 冠悦®
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	Flat Type(blue)
Classification ..... :	Type IIR

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (5 pages)	
Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shenzhen) Co., Ltd.** 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Clause 5.2.2 Bacterial filtration efficiency (BFE) Clause 5.2.3 Breathability Clause 5.2.4 Splash resistance Clause 5.2.5 Microbial cleanliness (Bioburden)	**Pony Testing International Group** 2/3/4/6F., Building 35, No.680, Guiping Road, Xuhui District, Shanghai, 200233, China

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See attachment.

Testing

Date of receipt of test item(s)……: See cover page

Dates of tests performed……: See cover page

Possible test case verdicts:

- test case does not apply to the test object …… : N/A
- test object does meet the requirement …… : P (Pass)
- test object was not evaluated for the requirement … : N/E (collateral standards only)
- test object does not meet the requirement …… : F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies)……: Same as the applicant

General product information:

1, The tested medical mask classified as type IIR.
2, The Biocompatibility (clause 5.2.6) is not evaluated in this test report.
3, The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		**P**
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type IIR	**P**
5	**Requirements**		**P**
5.1	**General**		**P**
5.1.1	**Materials and construction**		**P**
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	3 ply designed with two layers of polypropylene spunbonded non-woven fabric and one layer of polypropylene melt-blown non-woven fabric.	**P**
	The medical face mask shall not disintegrate, split or tear during intended use.		**P**
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		**P**
5.1.2	**Design**		**P**
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		**P**
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	With nose clip	**P**
5.2	**Performance requirements**		**P**
5.2.1	**General**		**P**
	All tests shall be carried out on finished products or samples cut from finished products.		**P**
5.2.2	**Bacterial filtration efficiency (BFE)**		**P**
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	See appended table 5.2.2	**P**
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.	Not such mask.	**N/A**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.	Same characteristics and same layer-composition declared by manufacturer.	**N/A**
	The lowest performing panel or area shall determine the BFE value of the complete mask	See above	**N/A**
5.2.3	**Breathability**		**P**
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	See appended table 5.2.3	**P**
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		**N/A**
5.2.4	**Splash resistance**		**P**
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.	See appended table 5.2.4	**P**
5.2.5	**Microbial cleanliness (Bioburden)**		**P**
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1).	See appended table 5.2.5	**P**
5.2.6	**Biocompatibility**		**N/E**
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.	The biocompatibility is not evaluated in this test report.	**N/E**
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime.		**N/E**
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		**N/E**
	The test results shall be available upon request.		**N/E**
6	**Marking, labelling and packaging**		**P**
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See attachment.	**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	The following information shall be supplied:		**P**
	a) number of this European Standard;		**P**
	b) type of mask (as indicated in Table 1).		**P**
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2	TABLE: Bacterial filtration efficiency (BFE)							P
Batch/ lot no.:	**Test Specimen no.:**	**Dimension of the test specimen L x W (mm x mm)**	**test area (cm²)**	**Flow rate (l/min)**	**Mean of the total plate counts of the two positive controls**	**Mean plate count of the negative controls**	**BFE for each test specimen (%)**	**Remarks**
20042801	1	155x130	132.7	28.3	1936	0	99.8	--
	2	155x130	132.7	28.3			99.8	--
	3	155x130	132.7	28.3			99.9	--
	4	155x130	132.7	28.3			99.7	--
	5	155x130	132.7	28.3			99.7	--

Supplementary information:
1, Each specimen was conditioned at 21.3 °C and 85.0 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: inside of mask.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.3	TABLE: Breathability (Differential pressure)				P
Batch/ lot no.:	**Test Specimen number-Test area number**	**Differential pressure for each test area (Pa/cm²)**	**The averaged differential pressure for each test specimen (Pa/cm²)**	**Flow rate (l/min)**	**Remarks**
20042801	1-1	22.8	22.5	8.0	--
	1-2	24.6		8.0	--
	1-3	20.8		8.0	--
	1-4	23.2		8.0	--
	1-5	20.9		8.0	--
	2-1	23.1	23.2	8.0	--
	2-2	21.8		8.0	--
	2-3	23.6		8.0	--
	2-4	22.3		8.0	--
	2-5	25.1		8.0	--
	3-1	27.7	28.0	8.0	--
	3-2	26.1		8.0	--
	3-3	27.5		8.0	--
	3-4	29.7		8.0	--
	3-5	28.9		8.0	--
	4-1	22.8	22.6	8.0	--
	4-2	23.9		8.0	--
	4-3	22.8		8.0	--
	4-4	20.9		8.0	--
	4-5	22.6		8.0	--
	5-1	19.2	19.7	8.0	--
	5-2	20.8		8.0	--
	5-3	20.5		8.0	--
	5-4	19.8		8.0	--
	5-5	18.4		8.0	--

Supplementary information:
Each specimen was conditioned at 21.0 °C and 1.05 % relative humidity for 4 h to bring them into equilibrium with

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

atmosphere prior to testing.

5.2.4	TABLE: Splash resistance			P
Batch/ lot no.:	**Test mask no.:**	**The material of tested mask**	**Test result (Pass/fail)**	**Remarks**
20042801	**1**	**See clause 5.1.1 for detail**	**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**	--

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

	29		**Pass**	**--**
	30		**Pass**	**--**
	31		**Pass**	**--**
	32		**Pass**	**--**

Supplementary information:

1, Each specimen was conditioned at 21.0 °C and 81.0 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

2, The description of target area tested: the centre of the specimen.

3, Any technique used to enhance visual detection of synthetic blood: cotton swab

4, The temperature and relative humidity for testing: 21.0 °C and 81.0 %

5, Description of any pre-treatment techniques used: N/A.

5.2.5	**TABLE: Microbial cleanliness (Bioburden)**			**P**
Batch/ lot no.:	**Mask(under test) no.:**	**Weight of each mask (g)**	**Total bioburden per individual mask (CFU/g)**	**Remarks**
20042801	**1**	**2.71**	**＜1**	**--**
	2	**2.74**	**＜1**	**--**
	3	**2.77**	**＜1**	**--**
	4	**2.79**	**＜1**	**--**
	5	**2.76**	**＜1**	**--**

Supplementary information:

End of EN 14683 test report

Product: Single-use medical face mask (non-sterile)

Type Designation: Flat Type(blue)

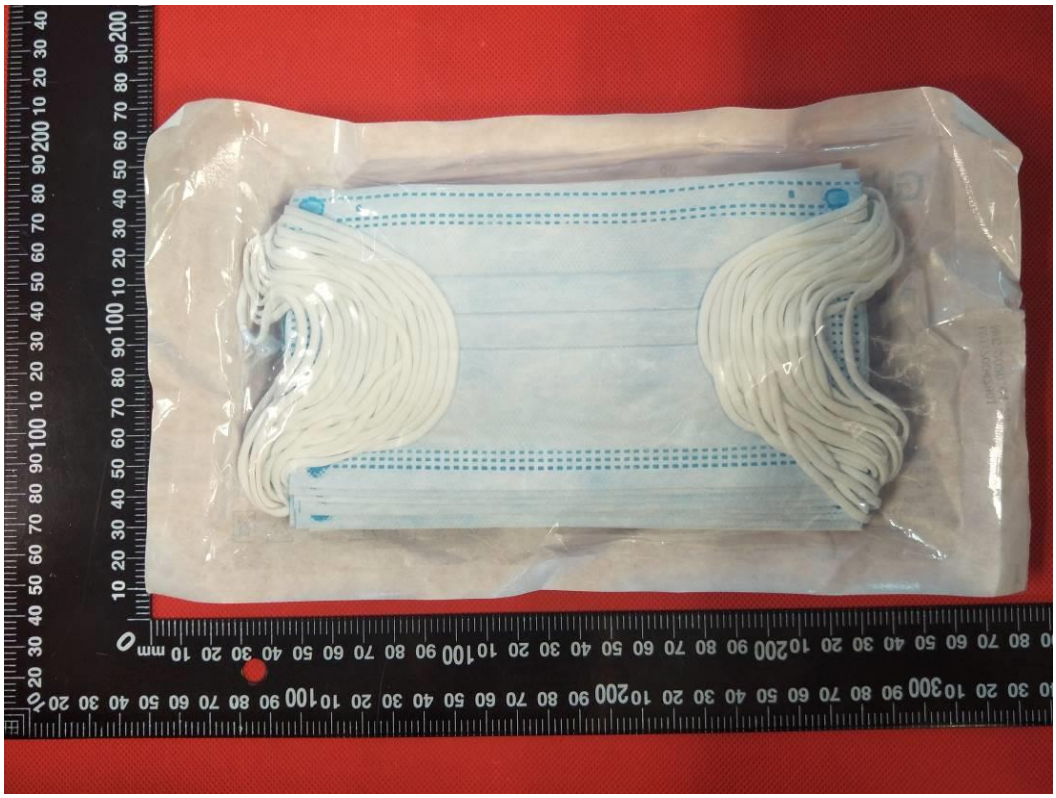

Figure 1 View of mask with packaging for test

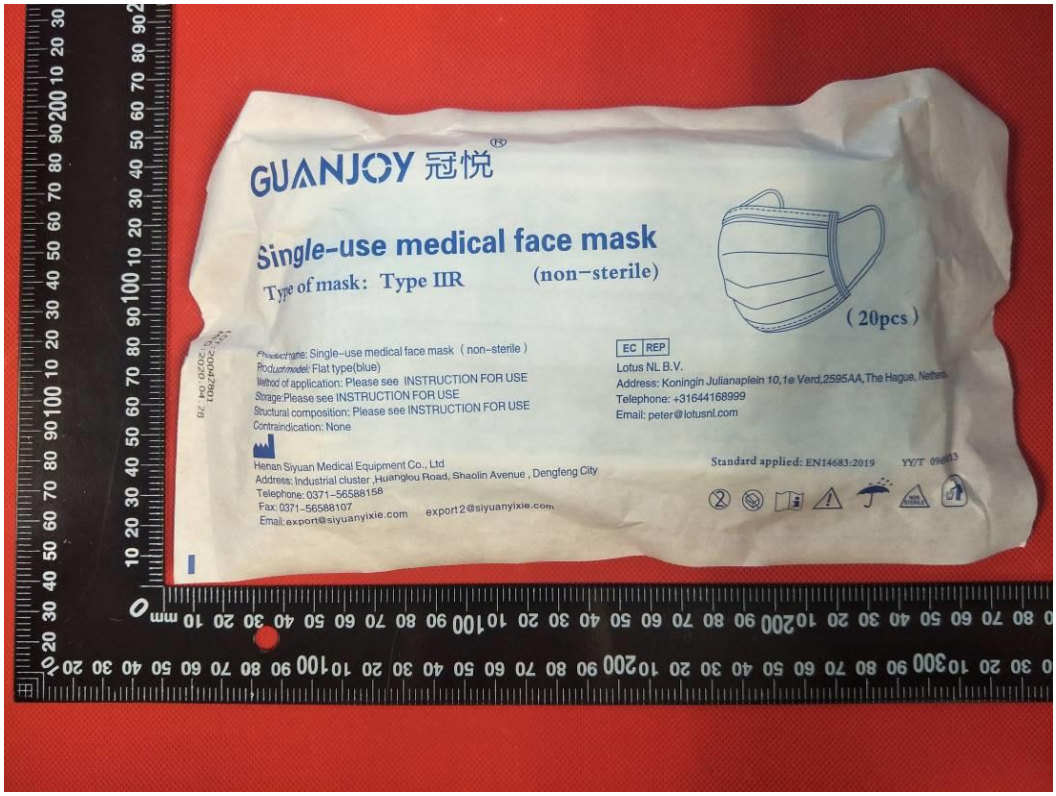

Figure 2 View of mask with packaging for test
(Final marking of package refer to Figure 7 to Figure 9 below)

Product: Single-use medical face mask (non-sterile)

Type Designation: Flat Type(blue)

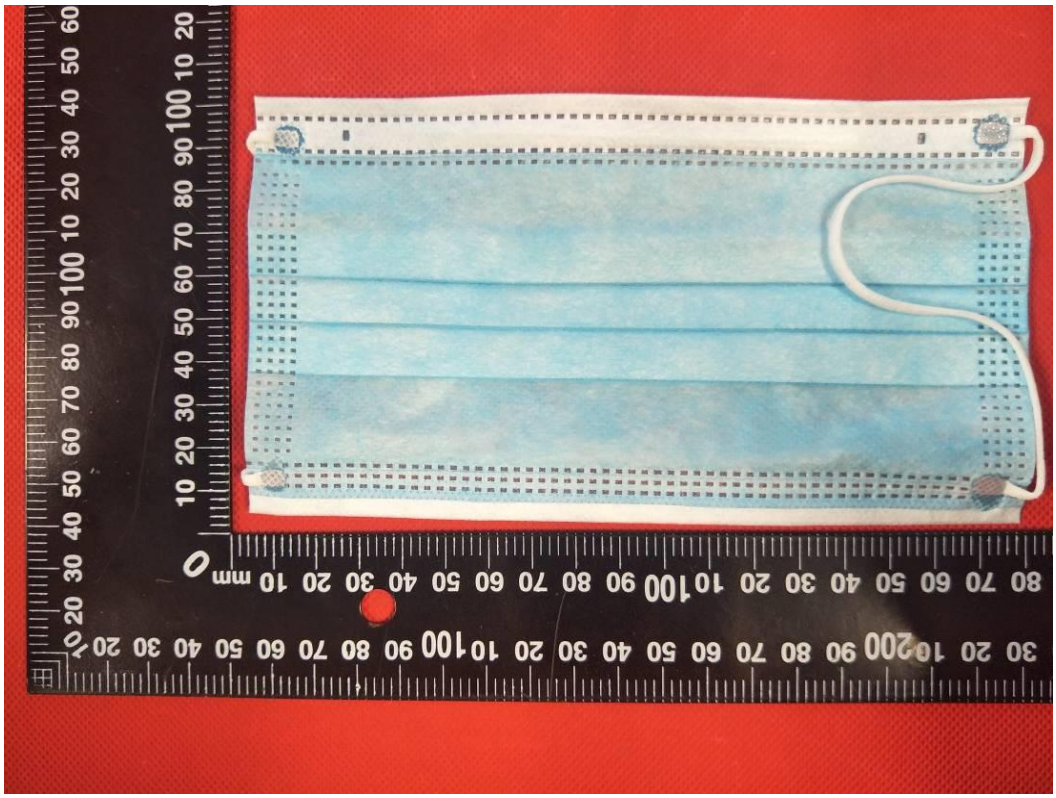

Figure 3 View of mask

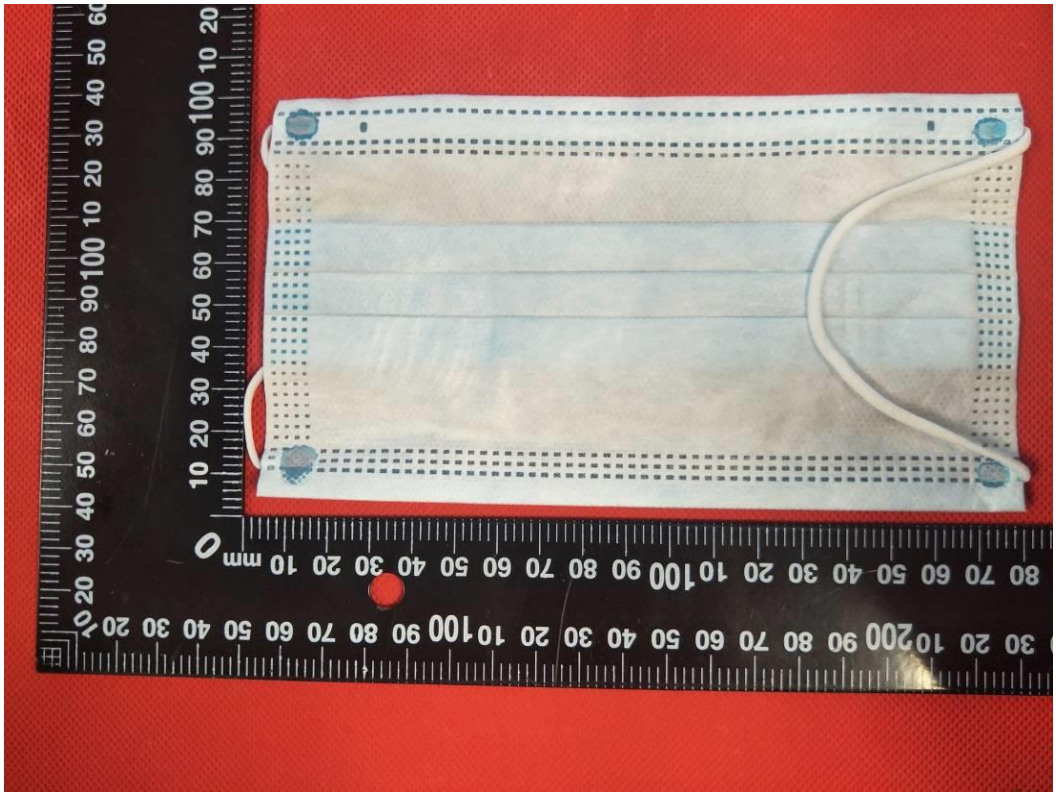

Figure 4 View of mask

Product: Single-use medical face mask (non-sterile)

Type Designation: Flat Type(blue)

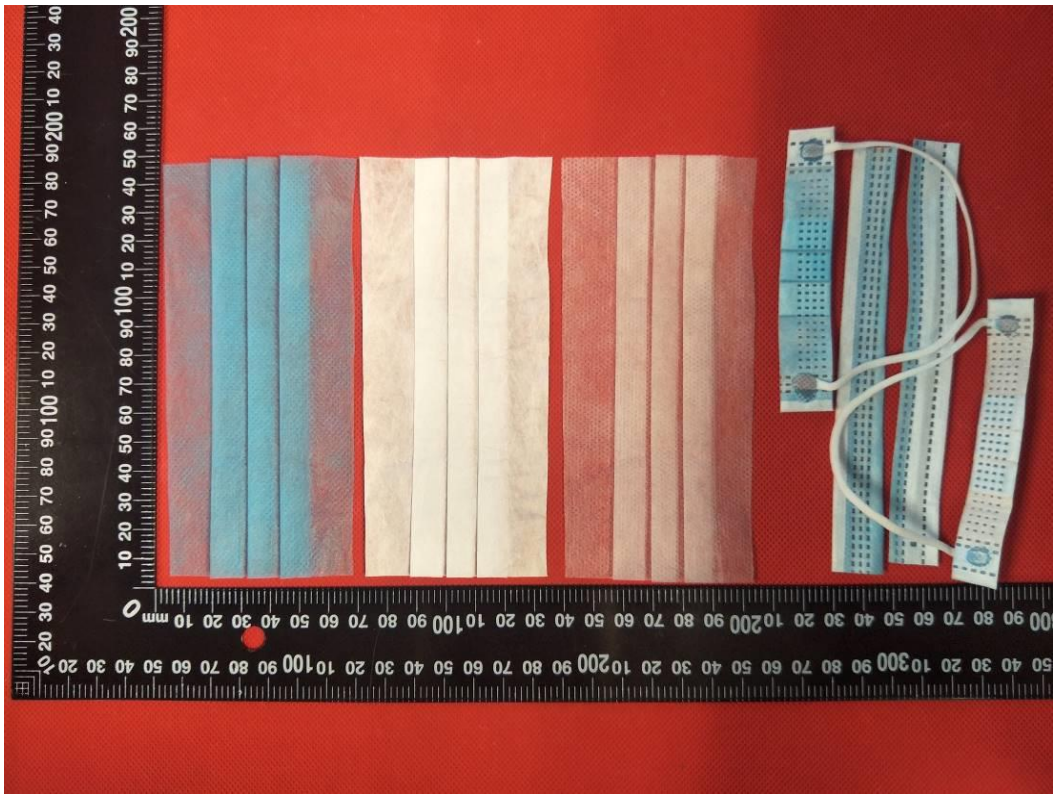

Figure 5 Inner view of mask – layers

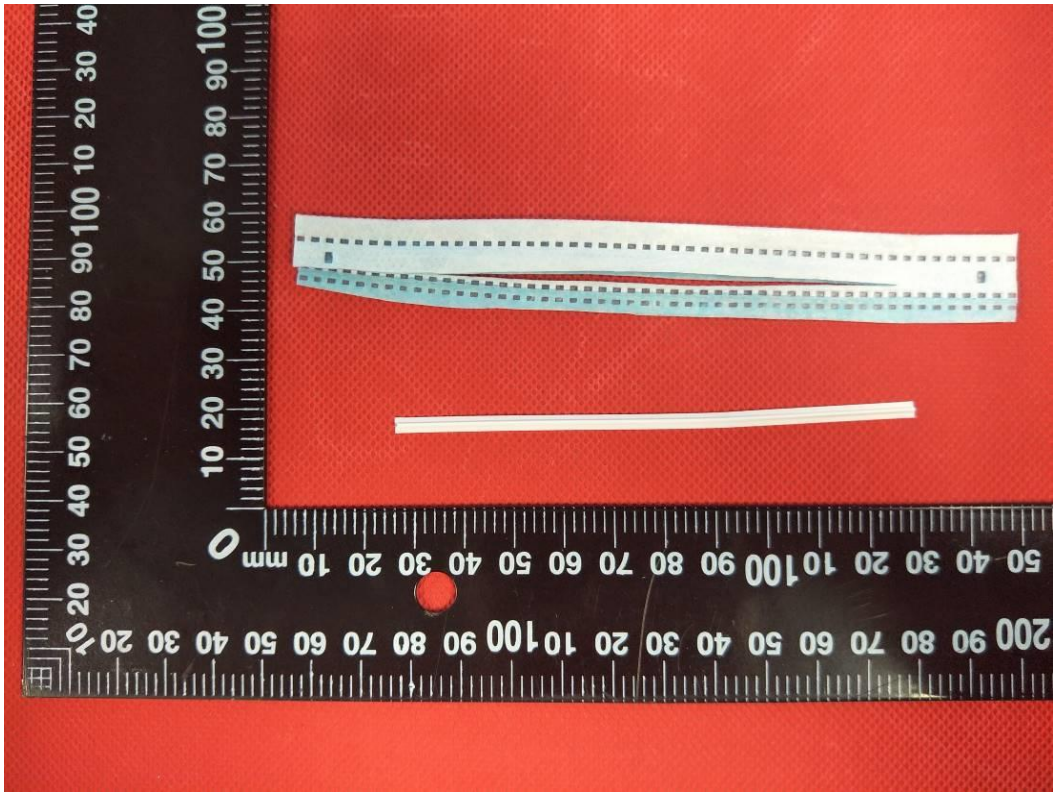

Figure 6 Inner view of mask – nose clip

Product: Single-use medical face mask (non-sterile)

Type Designation: Flat Type(blue)

Figure 7 View of packaging bag (20pcs/bag, which pack without instruction for use)

Figure 8 View of packaging bag 2 (20pcs/bag, which pack with instruction for use)

Product: Single-use medical face mask (non-sterile)

Type Designation: Flat Type(blue)

CE

INSTRUCTION FOR USE

Single-use medical face mask （non-sterile）

Please read the instruction book carefully before using

Edition: 1.1 28-04-2020

Overview: This product is used for clinical use by all kinds of people. The product consists of a mask body, a nose clip and two mask belts. The inner and outer layers of the product are made of polypropylene spunbonded non-woven fabric, and the intermediate layer is made of polypropylene filter material melt-blown non-woven fabric. The nose clip is made of galvanized iron wire and polythene bag. The mask belt is made of low elastic polyester fiber and fibrous material.

Product name: Single-use medical face mask （non-sterile）

Model: Folded Type

Intended use: During non-invasive operation, medical personnel or other relevant personnel wear the belt to cover the user's mouth, nose and jaw, providing a certain physical barrier to prevent the direct passage of pathogens, microorganisms and particles.

Contraindication and warning: None

Attention:

1.Products for single-use, do not reuse.
2.Check the integrity of the package before use. If the package is damaged, do not use it.
3.The product should be used as soon as possible after opening.
4.The mask should be replaced in time after it is wet and contaminated by the patient's blood and body fluids.

The performance characteristics of the device:

1.Bacterial filtration efficiency (BFE) ≥ 98%
2.Differential pressure < 60 Pa/cm2
3.Splash resistance pressure ≥ 16.0 kPa
4.Microbial cleanliness ≤ 30 cfu/g

Method

1.Place the front of the mask on the muzzle of the face. One end of the metal strip is above the mask, do not wear it upside down.
2.Place the mask across the nose and mouth of the face, and hang the rope on the ears with both hands.
3.Press the metal strips on both sides of the bridge of the nose with both hands to make the upper end of the mask close to the bridge of the nose. Then pull the mask down so it doesn't wrinkle and better covers the nose and mouth.

Storage

The relative temperature should not exceed 40℃ and the humidity should not exceed 80%. It should be kept in a cool, dry and well-ventilated environment without corrosive gases.

Transportation

The product should be handled gently in the process of transportation, to avoid falling from more than 2 meters to guard against pressure, direct sunlight and rain and snow.

Product Valid Date

2 years.

Applicable technical standards

EN 14683:2019+AC Medical face mask – Requirement and test methods

Manufacturer

Company name：Henan Siyuan Medical Equipment Co., Ltd
Address: Industrial cluster, Huanglou Road, Shaolin Avenue, Dengfeng City, China
Telephone: 0371-56588158
Fax: 0371-56588107
Email：export@siyuanyixie.com export2@siyuanyixie.com

European Authorized Representative

Company name：Lotus NL B.V.
Address：Koningin Julianaplein 10,1e Verd,2595AA,The Hague, Netherlands.
TEL：+31644168999

Label identification:

LOT	Batch number		Please don't reuse it
	Please read the instruction book carefully before using		Validity
	Warning and attention, please refer to the instructions for use		Manufacturer
EC REP	European Authorized Representative		Keep dry
NON STERILE	Non-sterile		Do not use if package is damaged
	Date of manufacture：XXXX-XX-XX		
CE	The product meets the basic requirements of European in REGULATION (EU) 2017/745		

Figure 9 Instruction for use

END OF THE PHOTO DOCUMENTATION