


Prüfbericht-Nr.: <i>Test Report No.:</i>	50356235 001	Auftrags-Nr.: <i>Order No.:</i>	244225293	Seite 1 von 15 Page 1 of 15
Kunden-Referenz-Nr.: <i>Client Reference No.:</i>	2166538	Auftragsdatum: <i>Order date:</i>	26.03.2020	
Auftraggeber: <i>Client:</i>	ZHEJIANG XIELI SCIENCE AND TECHNOLOG CO.,LTD NO.19-133 CENDONG ROAD, LONGGANG TOWN,WENZHOU CITY Zhejiang P.R. China			
Prüfgegenstand: <i>Test item:</i>	Disposable surgical mask			
Bezeichnung / Typ-Nr.: <i>Identification / Type No.:</i>	Flat type			
Auftrags-Inhalt: <i>Order content:</i>	Type test			
Prüfgrundlage: <i>Test specification:</i>	EN 14683:2019+AC:2019 (except for Clause 5.2.6 Biocompatibility)			
Wareneingangsdatum: <i>Date of receipt:</i>	27.03.2020			
Prüfmuster-Nr.: <i>Test sample No.:</i>	A002801368-001			
Prüfzeitraum: <i>Testing period:</i>	27.03.2020 to 08.04.2020			
Ort der Prüfung: <i>Place of testing:</i>	TÜV Rheinland (Shanghai) Co., Ltd.			
Prüflaboratorium: <i>Testing laboratory:</i>	TÜV Rheinland (Shanghai) Co., Ltd.			
Prüfergebnis*: <i>Test result*:</i>	Pass			
geprüft von / tested by:		kontrolliert von / reviewed by:		
10.04.2020 Rainbow Pan/PE		10.04.2020 Xiaojun Ding/Reviewer		
Datum <i>Date</i>	Name/Stellung <i>Name/Position</i>	Unterschrift <i>Signature</i>	Datum <i>Date</i>	Name/Stellung <i>Name/Position</i>
Sonstiges / Other:				
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>				
Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>				
* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend
	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
	P(ass) = passed a.m. test specification(s)	F(ail) = failed a.m. test specification(s)	N/A = not applicable	5 = poor
				N/T = not tested
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i>				

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. :	See cover page
Date of issue :	See cover page
Total number of pages :	See cover page
Testing Laboratory :	TÜV Rheinland (Shanghai) Co., Ltd.
Address :	No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China
Applicant's name	ZHEJIANG XIELI SCIENCE AND TECHNOLOG CO.,LTD
Address :	NO.19-133 CENDONG ROAD, LONGGANG TOWN, WENZHOU CITY Zhejiang P.R. China
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 :	Disposable surgical mask
Trade Mark	
Manufacturer	Same as applicant
Model/Type reference :	Flat type
Classification :	Type II

List of Attachments (including a total number of pages in each attachment):
N/A
Summary of testing:
Tests performed (name of test and test clause): Clause 5.2.2 Bacterial filtration efficiency; Clause 5.2.3 Breathability; Clause 5.2.5 Microbial cleanliness and construction check were performed on test sample.

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. Label:

EN 14683:2019 **Type II**



Disposable surgical mask



[Model] Flat type

[Structure] Composed of nonwoven fabric layer, filter material(melt-blown fabric), nose clip and mask belt.

[Application Scope] For clinical medical personnel to wear it during invasive operation, covering the user's mouth, nose and jaw, providing a physical barrier to prevent the direct penetration of pathogens, microorganisms, body fluid particles, etc

[Usage]

1. Check whether the packaging is intact before use.
2. Open the package and take out the mask. The mask has two sides. When wearing the mask, the white side is facing in, and the metal strip is facing up.
3. Hang the ear rope around the ears, adjust the bridge of the nose and press it in.
4. Then spread the mask up and down to completely cover the nose and mouth.

[Contraindication, note, warning and notice]

- 1) The valid period of the product is 2 years; please use within valid period.
- 2) Do not use the product if you are allergic to it.
- 3) This product is for one-time use. Dispose of it according to the requirements of medical waste management.
- 4) Hands are disinfected (full hand disinfection) after mask removal.
- 5) A mask is worn covering the nose and mouth of the wearer, at no time a mask is hanging around the neck of the wearer.
- 6) A used mask should be disposed of when no longer needed or between two procedures; when there is a further need for protection a new mask should be put on.

[Storage] The product should be stored at room temperature and relative humidity of no more than 80%, with good ventilation and no corrosive gas, with fire prevention, anti-theft, anti-rodent, anti-pest facilities.

[Package] 10pcs/bag



See small package seal



See small package seal



See small package seal



Zhejiang XieLi Science and Technology CO.,LTD
NO.19-133 CenDong Road, LongGang Town, WenZhou City, China

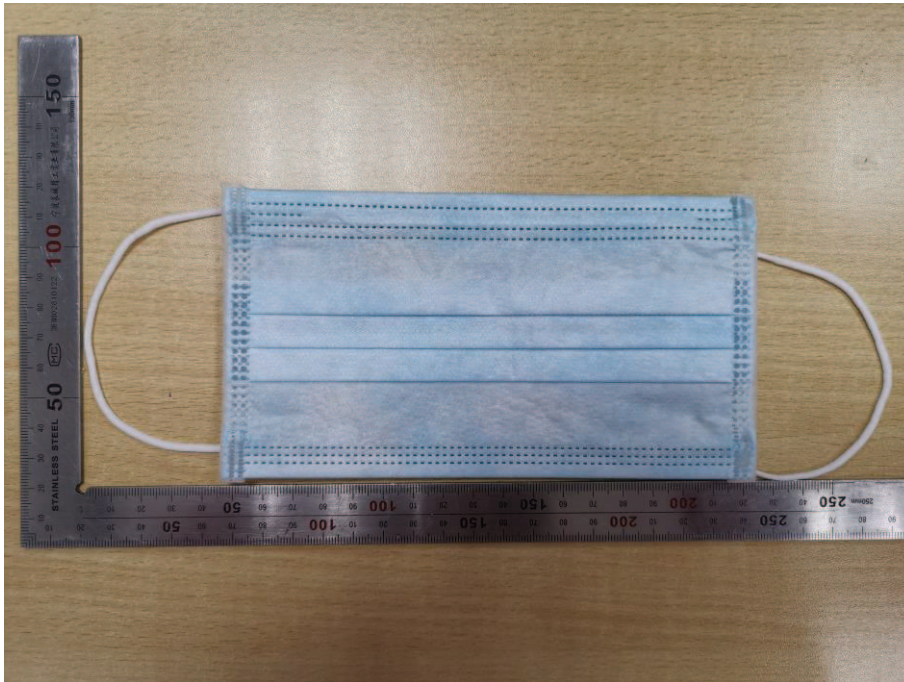


Share Info Consultant Service LLC Repräsentanzbüro
Heerdter Lohweg 83, 40549 Düsseldorf

Box:



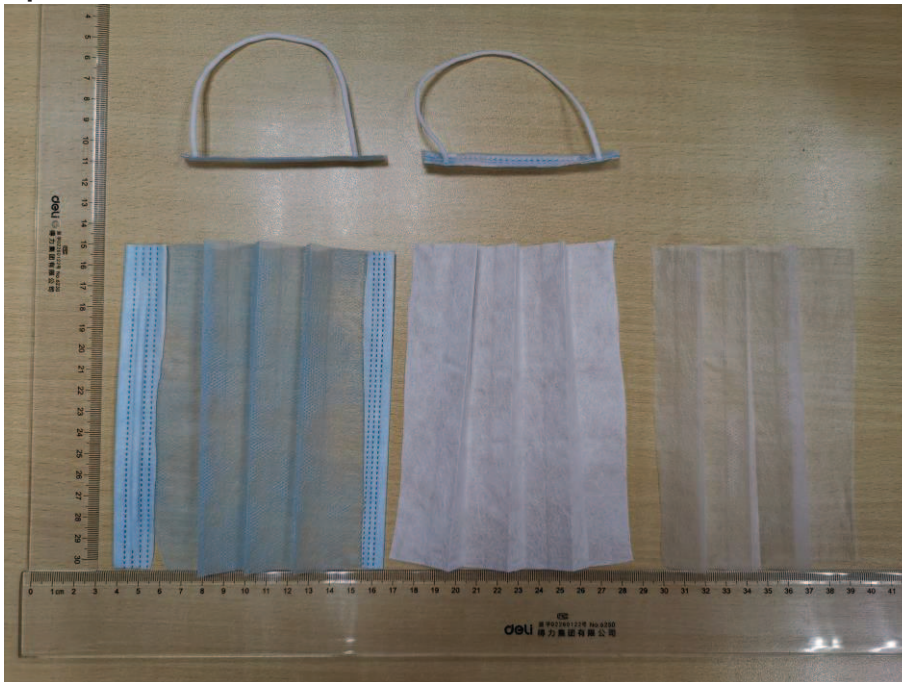
Front view of face mask:



Back view of face mask:



Open view of face mask:



Open view of face mask:



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 applicant

General product information:

The submitted samples are type II, non-sterile disposable surgical mask which is intended to use for filtering particulate matter in the air and blocking droplets, blood, body fluids and secretions in the medical working environment.

Clause 5.2.6 Biocompatibility is not evaluated in this test report.

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 II	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.	Composed of a filter layer between layers of fabric	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Complied	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Considered	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.	Fitted closely over nose	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 a nose bridge	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.	Complied	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 thick and rigid 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.	No such condition	N/A
	The lowest performing panel or area shall determine the BFE value of the complete mask		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).	No such respiratory protective device	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.		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.	Checked and complied	P
	The following information shall be supplied:		P
	a) number of this European Standard;	Marked on the label	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	b) type of mask (as indicated in Table 1).	Marked on the label	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	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 Speci- men no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm ²)	Flow rate (l/min)	The plate counts of the positive control	The plate counts of the test specimen	Mean plate count of the negative controls	BFE for each test specimen (%)	Remark s	
A00280 1368- 001 Lot:200 313	1	162x154	63.6	28.3	2010	11	0	99.45%	P	
	2	162x155	63.6	28.3	1952	8		99.59%	P	
	3	162x156	63.6	28.3	1935	10		99.48%	P	
	4	162x157	63.6	28.3	1911	10		99.48%	P	
	5	163x156	63.6	28.3	2017	15		99.26%	P	
Supplementary information: 1, Each specimen was conditioned at <u>21</u> °C and <u>85</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing. 2, The side of the test specimen was facing towards the challenge aerosol: <u>out side of mask</u>										

5.2.3		TABLE: Breathability (Differential pressure)				P
Batch/ lot no.:	Test Specimen number- Test area number	Differential pressure for each test area (Pa/cm ²)	The averaged differential pressure for each test specimen (Pa/cm ²)	Flow rate (l/min)	Remarks	
A0028 01368- 001 Lot:20 0313	1-1	28.7	33.0	8.0	P	
	1-2	33.3		8.0	P	
	1-3	36.8		8.0	P	
	1-4	32.2		8.0	P	
	1-5	34.2		8.0	P	
	2-1	30.2	33.2	8.0	P	
	2-2	36.0		8.0	P	
	2-3	35.2		8.0	P	
	2-4	33.5		8.0	P	
	2-5	30.9		8.0	P	
	3-1	30.0	32.3	8.0	P	
	3-2	37.4		8.0	P	

EN 14683:2019+AC:2019					
Clause	Requirement + Test		Result - Remark		Verdict
	3-3	28.0		8.0	P
	3-4	31.9		8.0	P
	3-5	34.4		8.0	P
	4-1	32.0	29.1	8.0	P
	4-2	26.6		8.0	P
	4-3	33.5		8.0	P
	4-4	25.3		8.0	P
	4-5	28.0		8.0	P
	5-1	29.5	31.1	8.0	P
	5-2	31.8		8.0	P
	5-3	30.2		8.0	P
	5-4	30.8		8.0	P
	5-5	33.3		8.0	P
Supplementary information:					
Each specimen was conditioned at <u>21</u> °C and <u>85</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing.					

5.2.4	TABLE: Splash resistance				N/A
Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks	
	1	--	--	--	
	2	--	--	--	
	3	--	--	--	
	4	--	--	--	
	5	--	--	--	
	6	--	--	--	
	7	--	--	--	
	8	--	--	--	
	9	--	--	--	
	10	--	--	--	
	11	--	--	--	
	12	--	--	--	

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
	13	--	--	--
	14	--	--	--
	15	--	--	--
	16	--	--	--
	17	--	--	--
	18	--	--	--
	19	--	--	--
	20	--	--	--
	21	--	--	--
	22	--	--	--
	23	--	--	--
	24	--	--	--
	25	--	--	--
	26	--	--	--
	27	--	--	--
	28	--	--	--
	29	--	--	--
	30	--	--	--
	31	--	--	--
	32	--	--	--
Supplementary information: 1, Each specimen was conditioned at ___°C and ___ % relative humidity for ___h to bring them into equilibrium with atmosphere prior to testing. 2, The description of target area tested: _____. 3, Any technique used to enhance visual detection of synthetic blood: _____. 4, The temperature and relative humidity for testing: ___°C and ___ % 5, Description of any pre-treatment techniques used: _____				

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

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
A002801368-001 Lot:200313	1	3.2	24	P
	2	3.1	9	P
	3	3.1	5	P
	4	2.8	16	P
	5	3.0	28	P
Supplementary information:				

End of test report