Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

SHANDONG QINGZE NONWOVEN FABRIC PRODUCTS CO,LTD.

Gaoze Industrial Park,Wulian County

Rizhao, Shandong, 262313, CHINA

DUNS Number:

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10065379

Listing No.	Product Code:	Device Name:
D381270	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance Disposable Face Mask

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39. " Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

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UCL

UCL-REGSERVICE INC.
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For and on behalf of
UCL-REG SERVICE INC.

Authorized Signature(s)

Cert. No.: M20722
Issued Date: 29 March 2020
Expiration Date: 31 December 2020

Report No.: 20ZCTS0319011SP

TEST REPORT EN 14683 Medical face masks - Requirements and test methods	
Report Reference No	20ZCTS0319011SP
Tested by (+ signature)	King Hu
Approved by (+ signature)	Kevin Yang
Date of issue	March 30, 2020
Testing laboratory	Shenzhen ZCT Technology Co., Ltd
Address	3/F, Building 5, Hongsheng Industrial Zone, Bao'an Road, Xixiang Street, Bao'an District, Shenzhen, Guangdong, China
Applicant's name	Shandong Qingze Nonwoven Fabric Products Co., Ltd.
Address	Gaoze Industrial Park, Wulian County, Rizhao City, Shandong Province, China
Manufacturer's name Address	Shandong Qingze Nonwoven Fabric Products Co., Ltd. Gaoze Industrial Park, Wulian County, Rizhao City, Shandong Province, China
Factory's name Address	Same as manufacturer
Test specification:	
Standard	☒ EN 14683:2019
Test procedure	Commission test
Non-standard test method	N/A
Test Report Form No	EN 14683
TRF Originator	SBD
Master TRF	Dated 2017-01
Test item description	Disposable Face Mask
Trade Mark	Multicolor Cutestar
Model/Type reference	Plane type
Ratings	Type IIR.

Test item particulars:	
Test case verdicts:	
Test case does not apply to the test object ...	N/A
Test object does meet the requirement	Pass (P)
Test object does not meet the requirement ...	Fail (F)
Testing:	
Date of receipt of test item	March 20, 2020
Date(s) of performance of test	March 20, 2020 to March 30, 2020
General remarks	
The test results presented in this report relate only to the item(s) tested.	
This report shall not be reproduced, except in full, without the written approval of the testing laboratory.	
"(see remark #)" refers to a remark appended to the report.	
"(see Annex #)" refers to an annex appended to the report.	
"(see appended table)" refers to a table in the Test Report.	
Throughout this report a comma (point) is used as the decimal separator.	

Copy of marking plate	
Disposable Face Mask Model: Plane type Shandong Qingze Nonwoven Fabric Products Co.,Ltd. Gaoze Industrial Park, Wulian County, Rizhao City, Shandong Province, China	No marking
Remark on the marking plate: 1. The height of graphical symbols is not less than 5 mm; 2. The height of letters and numerals are not less than 2 mm	

EN 14683			
Clause	Requirement - Test	Result - Remark	Verdict
4	**Classification**		-
	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.	Type IIR.	P
	The 'R' signifies splash resistance.		P
5	**Requirements**		-
5.1	**General**		-
5.1.1	**Materials and construction**		-
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of 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**		-
	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).		P
5.2	**Performance requirements**		-
5.2.1	**General**		-
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	**Bacterial filtration efficiency (BFE)**		-
	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.	For details, see table 1	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		P

EN 14683			
Clause	Requirement - Test	Result - Remark	Verdict
	impactor		
	In these cases, another valid equivalent method shall be used to determine the BFE.		P
	When a mask consists of two or more areas with different characteristics or different layercomposition, each panel or area shall be tested individually.		P
	The lowest performing panel or area shall determine the BFE value of the complete mask.		P
5.2.3	**Breathability**		-
	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.		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.		P
	In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		P
5.2.4	**Splash resistance**		-
	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		P
5.2.5	**Microbial cleanliness (Bioburden)**		-
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1).		P
	NOTE EN ISO 11737-1:2018 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.		-
	To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as		-

EN 14683			
Clause	Requirement - Test	Result - Remark	Verdict
	described in Annex D		
	The number of masks that shall be tested is minimum 5 of the same batch/lot.		P
	Other test conditions as described in EN ISO 11737-1:2018 may be applied.		P
	In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.		P
5.2.6	**Biocompatibility**		-
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.		P
	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.		P
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		P
	The test results shall be available upon rquest.		P
5.2.7	**Summary of performance requirements**		-
	Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.		P
	Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings wit h similar requirements.		P
6	**Marking, labelling and packaging**		-
	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.		P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN 14683:2019	P
	b) type of mask (as indicated in Table 2);	Type IIR For details, see table 2	P
	EN ISO15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

Table 1 - Performance requirements for medical face masks

Test Item	Requirement	Result	Verdict
Bacterial filtration efficiency (BFE), (%)		/	/
- Type I	≥ 95	/	/
- Type II	≥ 98	/	/
- Type IIR	≥ 98	99.5	P
Differential pressure (Pa/cm2)		/	/
- Type I	< 40	/	/
- Type II	< 40	/	/
- Type IIR	< 60	35	P
Splash resistance pressure (kPa)			
- Type I	Not required	/	
- Type II	Not required	/	
- Type IIR	≥ 16.0	18.7	P
Microbial cleanliness (cfu/g)			
- Type I	≤ 30	/	
- Type II	≤ 30	/	
- Type IIR	≤ 30	25	P

Table 2 Medical Face Mask Material Requirements by Performance Level

Characteristic	Requirement	Test Method	Result	Verdict
Bacterial filtration efficiency, %				
- Level 1 Barrier	>=95	ASTM F2100-19	/	/
- Level 2 Barrier	>=98	ASTM F2100-19	/	/
- Level 3 Barrier	>=98	ASTM F2100-19	99.5	P
Differential pressure, mm H_2O/cm^2				
- Level 1 Barrier	<5.0	ASTM F2100-19	/	/
- Level 2 Barrier	<6.0	ASTM F2100-19	/	/
- Level 3 Barrier	<6.0	ASTM F2100-19	5.2	P
Sub-micron particulate filtration efficiency at 0.1 micron, %				
- Level 1 Barrier	>=95	ASTM F2100-19	/	/
- Level 2 Barrier	>=98	ASTM F2100-19	/	/
- Level 3 Barrier	>=98	ASTM F2100-19	99.3	P
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result				
- Level 1 Barrier	80	ASTM F2100-19	/	/
- Level 2 Barrier	120	ASTM F2100-19	/	/
- Level 3 Barrier	160	ASTM F2100-19	175	P
Flame spread				
- Level 1 Barrier	Class 1	ASTM F2100-19	/	/
- Level 2 Barrier	Class 1	ASTM F2100-19	/	/
- Level 3 Barrier	Class 1	ASTM F2100-19	Class 1	P