REPORT

Applicant : Guangzhou Yunjing Biotechnology Co. , Ltd.

Address : Room 1006,10th floor, 11 and 13 Songbai East Street, Baiyun District, Guangzhou City, Guangdong Province

Manufacturer : Guangzhou Yunjing Biotechnology Co. , Ltd.

Address : Room 1006,10th floor, 11 and 13 Songbai East Street, Baiyun District, Guangzhou City, Guangdong Province

The following samples were submitted and identified by/on behalf of the client as：

Sample Name : Protective mask

Brand: : GAOJIE

Sample Model : KN95

Model May Cover : N95,KF94

Sample Received Date : Mar.10,2020

Testing Period : Mar.10,2020~ Mar.20,2020

Test Method : EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods

Test Result : Tests requested in accordance to client requirement

Note: 1.The ambient temperature of the test environment：22°C
2. This report is only responsible for the samples.
3. This test report is only used for CE certification conformity determination.

Report compiled: Yan Luo
Yan Luo / File administrators

Report issued: Zilu Jian
Zilu Jian / Technique principal

Report date: Mar, 20, 2020

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Test result:

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. The 'R' signifies splash resistance.	Type I	Pass
5	Requirements		/
5.1	General	/	Pass
5.1.1	Materials and construction The mical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulbetween layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness	Meet the requirements	Pass
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. Medical face masks may have different shapes and constructions as well as additional features such as 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).	Meet the requirements	Pass
5.2	Performance requirements	Meet the requirements	Pass
5.2.1	General All tests shall be carried out on finished products or samples cut from finished products.	/	/
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 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	BFE：98%	Pass

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	shall be used to determine the BFE. When a mask consists of two or more areas with different characteristics or different layer- composition, each panel or area shall btested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.		
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. 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)	Differential pressure：$52Pa/cm^2$	Pass
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.	Splash resistance pressure： 16.1kPa	Pass
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). To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in EN ISO 11737-1:2018 may be applied. In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.	Microbial cleanliness:30 cfu/g	Pass
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. The manufacturer shall comlete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.	/	/
5.2.7	Summary of performance requirements	/	/

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Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] 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. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

6	Marking, labelling and packaging		Pass
	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. The following information shall be supplied: a) number of this European Standard; b) b) type of mask (as indicated in Table 1). c) EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	Meet the requirements	Pass

Note: Part of the test project data is provided by the customer, not tested and verified

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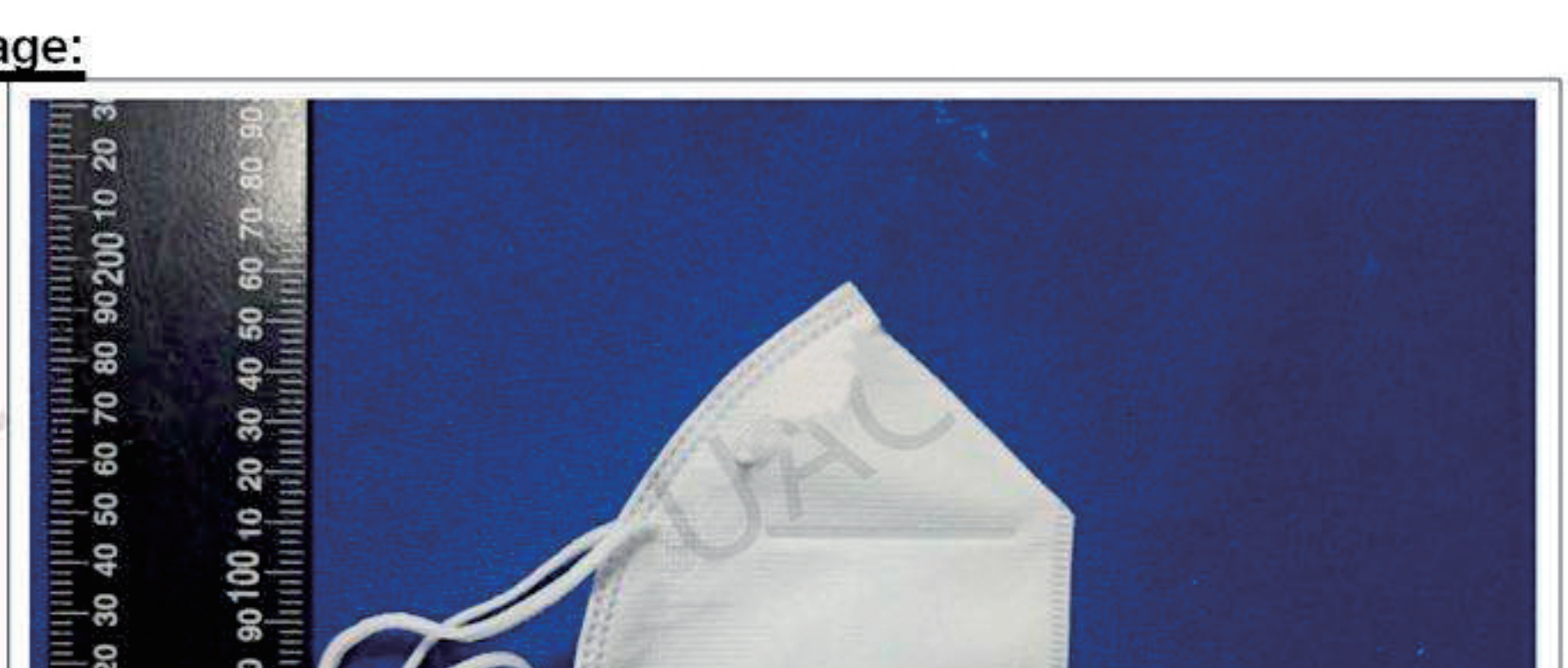
Sample image:



-------------- End of Report -------------

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