[redacted]

Sample Description	: MEDICAL FACE MASK
Style / Item No.	: JBK-01
Lot No.	: 20200315
Size	: 17.5cm X 9.5cm
Classification	: JBK-01 TYPE II
Country of Destination	: EUROPEAN UNION

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

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Sample Receiving Date	: Apr 09, 2020
Test Performing Date	: Apr 09, 2020 to Apr 27, 2020
Test Performed	: Selected test(s) as requested by applicant
Test Result(s)	:

Test Requested	Result
EN 14683:2019+AC:2019 excluding clause 6	Pass

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

scan to see the report

GZHL2004009722MD

Arthur Mak
Authorized Signatory

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Test Conducted: EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

Scope

This document specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

1.Sample name: Medical face mask

2.Sample description:

Classification	☐Type I	☑Type II	☐Type IIR (For type II, The 'R' signifies splash resistance)

3.Test Results: Details shown as following table

Clause	Test Item	Test Requirement / Test Method	Test Result
5 Requirement			
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. 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.	PASS See Table 1
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 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).	PASS See Table 2
5.2 Performance requirements			
5.2.1	General	All tests shall be carried out on finished products or samples cut from finished products.	PASS See Table 3

Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

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Clause	Test Item	Test Requirement / Test Method	Test Result
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 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 be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.	PASS See Table 4
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).	PASS See Table 5
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.	NA
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). 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 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.	PASS See Table 6

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<table>
<tr><th>Clause</th><th>Test Item</th><th>Test Requirement / Test Method</th><th>Test Result</th></tr>
<tr><td></td><td></td><td>In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.</td><td></td></tr>
<tr><td>5.2.6</td><td>Biocompatibility</td><td>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 complete 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.</td><td>PASS</td></tr>
<tr><td>5.2.7</td><td>Summary of performance requirements</td><td>Table 1 — Performance requirements for medical face masks
<table>
<tr><th>Test</th><th>Type I [a]</th><th>Type II</th><th>Type IIR</th></tr>
<tr><td>Bacterial filtration efficiency (BFE), (%)</td><td>≥ 95</td><td>≥ 98</td><td>≥ 98</td></tr>
<tr><td>Differential pressure (Pa/cm^2)</td><td>< 40</td><td>< 40</td><td>< 60</td></tr>
<tr><td>Splash resistance pressure (kPa)</td><td>Not required</td><td>Not required</td><td>≥ 16,0</td></tr>
<tr><td>Microbial cleanliness (cfu/g)</td><td>≤ 30</td><td>≤ 30</td><td>≤ 30</td></tr>
<tr><td colspan="4">[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.</td></tr>
</table></td><td>---</td></tr>
<tr><td colspan="4">6 Marking, labeling and packaging</td></tr>
<tr><td>---</td><td>---</td><td>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) type of mask (as indicated in Table 1).
EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.</td><td>NT</td></tr>
</table>

Remark:

1. NT = Not tested as per client's request;
2. NA = Not Applicable;
3. Above test was subcontracted to Guangzhou Quality Supervision and Testing Institute.

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Appendix:

Table 1

Materials and construction:

Requirement	Conclusion
The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Pass
The medical face mask shall not disintegrate, split or tear during intended use.	Pass
In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Pass

Table 2

Design:

Requirement	Conclusion
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.	Pass
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).	Pass

Table 3

General:

Requirement	Conclusion
All tests shall be carried out on finished products or samples cut from finished products.	Pass

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Table 4

Bacterial filtration efficiency (BFE):

Sample	BFE (%)	Requirement (%)	Classification	Conclusion
1	99.95	≥98 EN 14683:2019+AC:2019	Type II	Pass
2	99.95			
3	99.95			
4	99.95			
5	99.95			

Table 5

Breathability:
Differential pressure

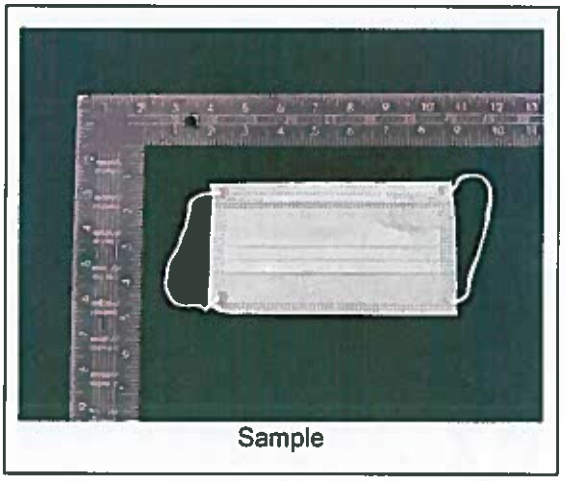
Sample	Differential pressure (Pa/cm^2)	Requirement (Pa/cm^2)	Classification	Conclusion
1	34.7	< 40 EN 14683:2019+AC:2019	Type II	Pass
2	32.8			
3	33.6			
4	33.2			
5	38.2			
Average	34.5			

Table 6

Microbial cleanliness (Bioburden):

Sample	Measured Value (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
1	21	≤30 EN 14683:2019+AC:2019	Type II	Pass
2	21			
3	16			
4	26			
5	22			

Sample Photo(s):



Sample

End of Report

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