APPLICATION FOR MEDICAL DEVICE REGULATION

On Behalf of

Jiangsu Guangda Medical Material Group Co., Ltd.

Disposable Surgical Face Mask
17.5cmx9.5cm-3ply

Prepared for : Jiangsu Guangda Medical Material Group Co., Ltd.
No.18 Baochang Road(N), Libao Town, Haian County,
Jiangsu Province,China 226631

Prepared By : Shenzhen HTT Technology Co., Ltd.
1F, B Building, Huafeng International Robotics Industrial Park,
Gushu, Xixiang Street, Bao'an District, Shenzhen

Date of Test:	**Mar.10,2020~Mar.16,2020**
Date of Report:	**Mar.16,2020**
Report Number:	**HTT202003270LR**

TEST REPORT

EN 14683: 2005

Surgical masks - Requirements and test methods

Report reference No ..... :	HTT202003270LR
Tested by (+ signature).....	Darek Wang
Approved by (+ signature).....	Kevin Yang
Date of issue :	Mar.16,2020
Testing Laboratory Name ..... :	Shenzhen HTT Technology Co., Ltd.
Address ..... :	1F, B Building, Huafeng International Robotics Industrial Park, Gushu, Xixiang Street, Bao'an District, Shenzhen
Testing location ..... :	CBTL ☐ CCATL ☐ SMT ☐ TMP ☐
Address..... :	Same as above.
Applicant's Name ..... :	Jiangsu Guangda Medical Material Group Co., Ltd.
Address ..... :	No.18 Baochang Road(N), Libao Town, Haian County, Jiangsu Province,China 226631
Standard..... :	EN 14683: 2005
Test procedure ..... :	MDD Approval
Procedure deviation ..... :	N/A
Non-standard test method ..... :	N/A
Product..... :	Disposable Surgical Face Mask
Manufacturer..... :	Jiangsu Guangda Medical Material Group Co., Ltd.
address..... :	No.18 Baochang Road(N), Libao Town, Haian County, Jiangsu Province,China 226631
Trademark..... :	
Model and/or type reference..... :	17.5cmx9.5cm-3ply
Rating(s)	N/A

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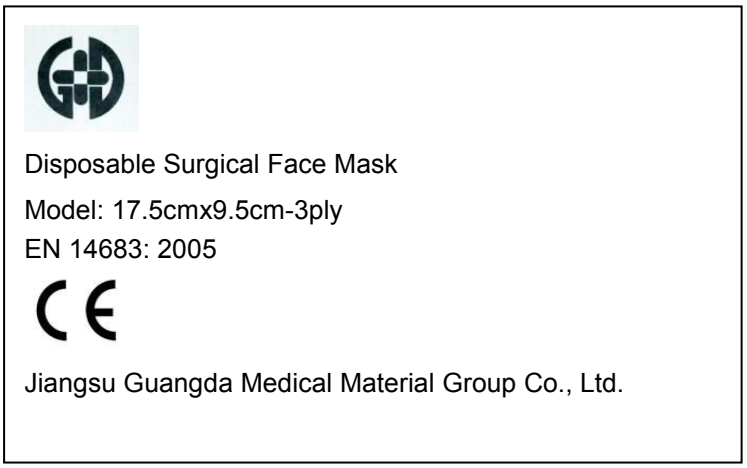
Test item particulars :	
Test case verdicts:	
Test case does not apply to the test object..... :	N(/A.)
Test item does meet the requirement..... :	P(ass)
Test item does not meet the requirement..... :	F(ail)
Testing:	
Date of receipt of test item	Mar.10,2020
Date(s) of performance of test	Mar.10,2020~Mar.16,2020

Label



Note:

1. The height of graphical symbols shall not be less than 5 mm;
2. The height of letters and numerals shall not be less than 2 mm;
3. The main rating label was attached in enclosure.

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General remarks: Clause number between brackets refer to clauses in EN 14683 "(see remark #)" refers to a remark appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a comma is used as the decimal separator. The test 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. When determining the test conclusion, the Measurement Uncertainty of test has been considered. . Unless otherwise specified, test are made under normal conditions at an ambient temperature within the range of 15℃ to 35℃, RH45% to 75% and an air pressure of 860mbar of 1060mbar	Attachment with: 1) Photo documentation

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EN 14683			
Clause	**Requirement-Test**	**Result**	**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. 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.		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).		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.	BFE: >98.0%	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.		N/A
	When a mask consists of two or more areas with different characteristics or different layercomposition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.		N/A
5.2.3	**Breathability**		P

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EN 14683			
Clause	**Requirement-Test**	**Result**	**Verdict**
	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.	Differential pressure:<40Pa/cm2	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**		N/A
	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.		N/A
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).	Microbial cleanliness:<30 CFU/g	P
	To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.		P
	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.		P
5.2.6	**Biocompatibility**		P
	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.		P
5.2.7	**Summary of performance requirements**		P

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<table>
<tr><th colspan="4">EN 14683</th></tr>
<tr><th>Clause</th><th>Requirement-Test</th><th>Result</th><th>Verdict</th></tr>
<tr><td></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><td>P</td></tr>
<tr><td>6</td><td>Marking, labelling and packaging</td><td></td><td>P</td></tr>
<tr><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.</td><td></td><td>P</td></tr>
<tr><td></td><td>The following information shall be supplied:
a) number of this European Standard;
b) type of mask (as indicated in Table 1).</td><td>EN 14683: 2005
Type II</td><td>P</td></tr>
</table>

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Appendix 1

Photo documentation

Photo 1

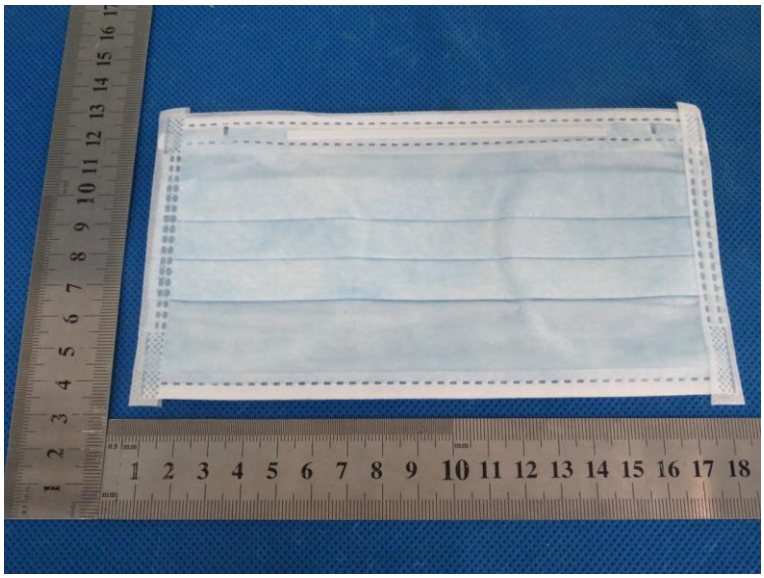
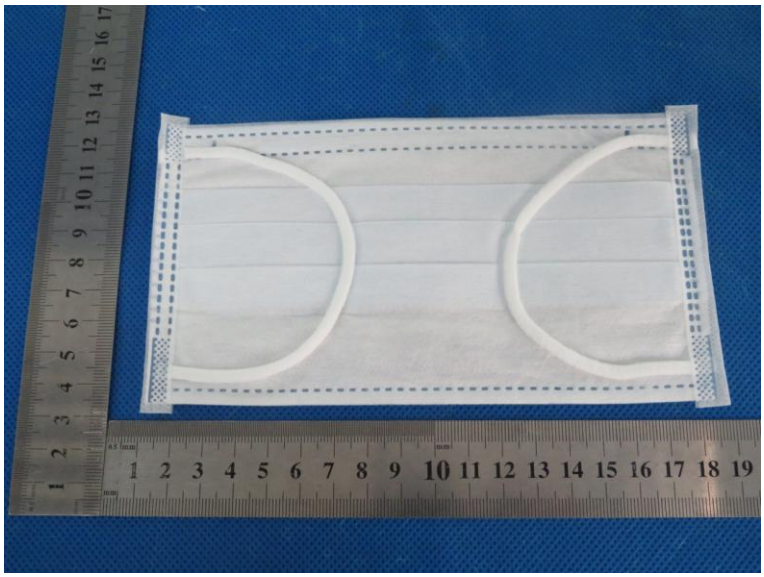


Photo 2



*****End of Test Report*****

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