TEST REPORT

EN 14683

Medical face masks - Requirements and test methods

Report Reference No.....:	BD-MDD407111
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Compiled by (name + signature) .....:	Chard Li
Approved by (name + signature).....:	Tom Zhang
Date of issue.....:	Apr. 07, 2020
Total number of pages .....:	6 Pages
Testing Laboratory.....:	**Shenzhen Beyon Certification Co.,Ltd.**
Address .....:	**4F Jiayunda Bulid Xinhua 1rd Baoan Shenzhen China**
Testing location .....:	As above
Applicant's name.....:	
Address .....:	
Test specification:	
Standard .....:	EN 14683:2019+AC:2019
Test procedure .....:	Type approved
Non-standard test method……..:	N/A
Test item description .....:	disposable medical mask
Trade Mark .....:	GuangLun
Manufacturer .....:	
Address .....:	
Model/Type reference .....:	GL-02

Summary of testing:	
Tests performed (name of test and test clause): All clauses.	**Testing location:** 10 buildings 1-5 floors of Xinligang Bay Industrial Zone, Huangtian Street, Baoan District, Shenzhen

Test item particulars .....:

Relative Humidity.....: 56% RH

Air Pressure .....: 97.9 kPa

Temperature by measurement .....: 25 °C

Information for safety use.....: N/A

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 does not meet the requirement.....: F (Fail)

Testing:

Date of receipt of test item .....: Apr. 01, 2020

Date (s) of performance of tests .....: Apr. 01, 2020 – Apr. 03, 2020

General remarks:

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 Issuing testing laboratory.
"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
Throughout this report a comma (point) is used as the decimal separator.
List of test equipment must be kept on file and available for review.
Manufactured under ISO9001&ENISO13485 certified quality system.

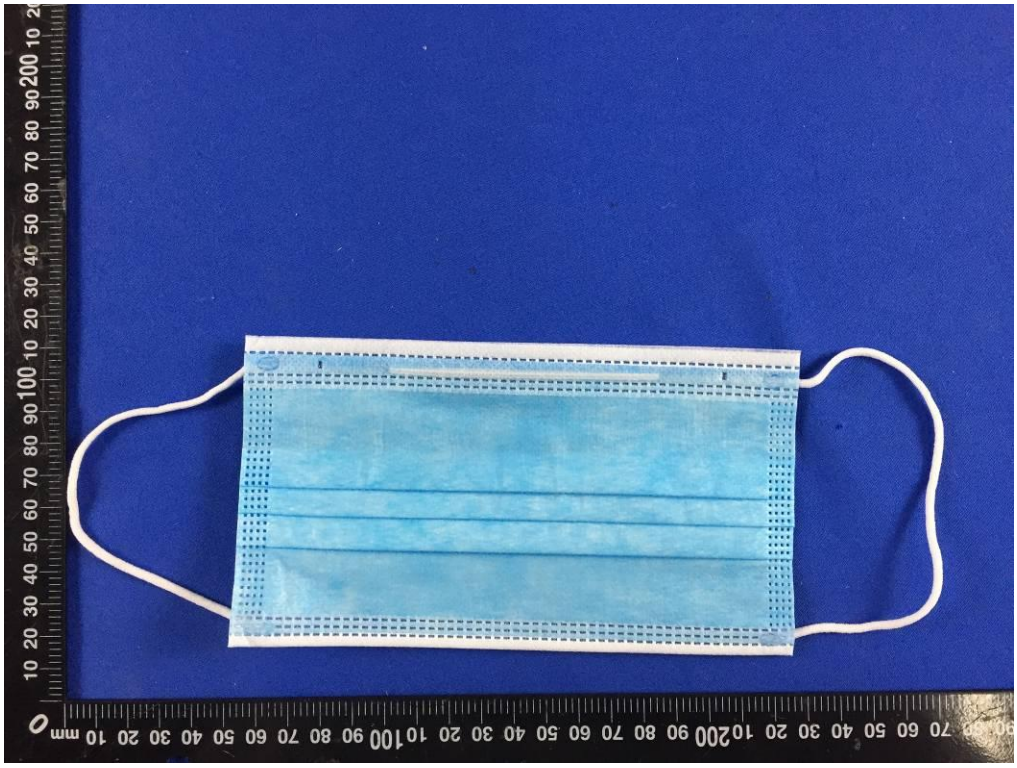
General product information:

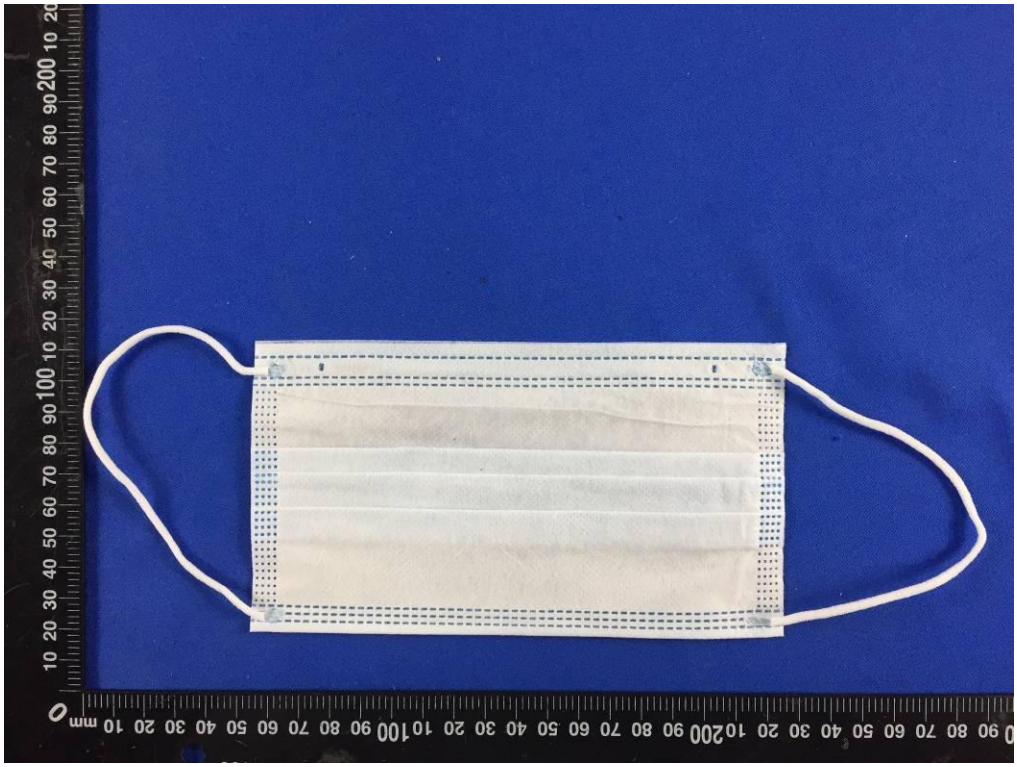
The following test were carried out according to EN 14683:2019+AC:2019 and manufacturer specification requirement.

EN 14683			
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	Type I	P
5	Requirements		P
5-1	General		P
5.1.1	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
5.1.2	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
5.2	Performance requirements		P
5.2.1	All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.		P
5.2.2	When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.		P
5.2.3	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
5.2.4	When tested in accordance with ISO 22609 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.	No required	N/A
5.2.5	When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be < 30 cfu/g tested (see Table 1).		P
5.2.6	According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact.		P
5.2.7	Summary of performance requirements		P

Test	Test Standard	Standard	Test Date	Value
Bacterial Filtration Efficiency: BFE	EN 14683:2019+AC:2019 (Annexe B)	≥95%(TypeI)	Apr. 01, 2020	97.4%min
Differential pressure	EN 14683:2019+AC:2019 (Annexe C)	<40Pa/cm²(TypeI)	Apr. 01, 2020	38,00max
SPLASH	ISO22609:2004	No required	Apr. 01, 2020	No required
Intracutaneous irritation test	ISO10993-10	No irritation	Apr. 02, 2020	No irritation
Cytotoxicity	ISO10993-5	No cytotoxicity	Apr. 02, 2020	No cytotoxicity
Sensitization	ISO10993-10 et-10A	Topical application: no sensitization	Apr. 02, 2020	Topical application: no sensitization
Sensitization	ISO10993-10 et-10A	Intradermal injection:no sensitization	Apr. 03, 2020	Intradermal injection: no sensitization
Microbial cleanliness CFU/g	EN ISO 11737-1:2018	≤30	Apr. 03, 2020	Compliant
Using time:BFE+ Differential pressure	EN 14683:2019+AC:2019 (AnnexeB&C)	≥95%(TypeI) <40Pa/cm²(TypeI)	Apr. 03, 2020	8h:>97.4% 8h:<38,00Pa/cm²

Photo document of product





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