TEST REPORT

Prepared For :	**GAUKE Healthcare Co., Ltd** Chengnan Industrial Park,TuanFeng County, Huang Gang city ,Huibei province China
Trade Mark :	**N/A**
Product Name :	**medical mask**
Model(s) :	**Non woven 3ply**
Prepared By:	**Shenzhen CCT Testing Technology Co., Ltd.** 8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China Tel: +86 755-3315 7675 Fax: +86 755-33609691 Email: cct@cct-prc.com Web: www.cct-prc.com
Test Date:	**Mar. 18, 2020 - Mar. 23, 2020**
Date of Report:	**Mar. 23, 2020**
Report No. :	**CCT20031808PRS**

Note: This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of Shenzhen CCT Testing Technology Co., Ltd.

TEST REPORT

EN 14683

Medical face masks- Requirements and test methods

Reference No. ..... :	CCT20031808PRS
Date of issue..... :	Mar. 23, 2020
Contents ..... :	9 pages
Testing laboratory	
Name..... :	Shenzhen CCT Testing Technology Co., Ltd.
Address ..... :	8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China
Testing location ..... :	Same as above
Client	
Name..... :	GAUKE Healthcare Co., Ltd
Address ..... :	Chengnan Industrial Park,TuanFeng County, Huang Gang city ,Huibei province China
Test specification	
Standard..... :	EN 14683:2019
Test procedure ..... :	CE- MDD
Procedure deviation ..... :	N.A.
Non-standard test method..... :	N.A.
Test item	
Description ..... :	medical mask
Trademark..... :	N/A
Model and/or type reference ..... :	Non woven 3ply
Manufacturer ..... :	GAUKE Healthcare Co., Ltd
Address ..... :	Chengnan Industrial Park,TuanFeng County, Huang Gang city ,Huibei province China

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. 18, 2020

Date(s) of performance of test..... From Mar. 18, 2020 to Mar. 23, 2020

General rN/Arks

This report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item(s) tested.

”(see rN/Ark #)" refers to a rN/Ark appended to the report.

"(see Annex #)" refers to an annex appended to the report.

Throughout this report a comma is used as the decimal separator.

Remark :

-This technical report is only used for internal reference of the company, and not for any other legal basis and use.

Copy of marking plate:

medical mask

Model： Non woven 3ply

GAUKE Healthcare Co., Ltd
Made in China

Summary of Testing:

The product meets **EN 14683** after test. The test result complies with the requirements of the relevant standard.

EN 14683:2019			
Clause	Requirement – Test	Result - Remark	Verdict
1	Scope		P
2	Normative references		P
3	Terms and definitions		P
3.1	medical face mask medical device covering the mouth and nose providing a barrier to minimise the direct transmission of infective agents between staff and patient		P
3.2	bacterial filtration efficiency (BFE) efficiency of the medical face mask material(s) as a barrier to bacterial penetration Note 1 to entry: The BFE test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials.		P
3.3	differential pressure air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity		P
3.4	colony forming unit (cfu) unit by which the culturable number of micro-organisms is expressed Note 1 to entry: The culturable number is the number of micro-organisms, single cells or aggregates, able to form colonies on a solid nutrient medium.		P
3.5	cleanliness freedom from unwanted foreign matter		P
3.5.1	cleanliness — microbial freedom from population of viable micro-organisms on a product and/or a package		P
3.5.2	cleanliness — particulate matter freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact		P
3.6	infective agent micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient, members of staff or other		P
3.7	surgical procedure surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions		P
3.8	aerosol		P

EN 14683:2019			
Clause	Requirement – Test	Result - Remark	Verdict
	gaseous suspension of solid and/or liquid particles, the particles having a negligible falling velocity Note 1 to entry: See EN 132. Note 2 to entry: This velocity is generally considered to be less than 0,25 m/s.		
3.9	filter material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air		P
3.10	splash resistance ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure		P
	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
5	Requirements		P
5.1	General		P
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	absence of particulate matter	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. 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)	Metal strip fixing	P
5.2	Performance requirements		P
5.2.1	General All tests shall be carried out on finished products or samples cut from finished		P

EN 14683:2019			
Clause	Requirement – Test	Result - Remark	Verdict
	products, if applicable in their sterile state		
5.2.2	Bacterial filtration efficiency (BFE)	Bacterial filtration	P
	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.	efficiency (BFE), (%) ≥ 98% Differential pressure (Pa/cm2) < 49 Microbial cleanliness (cfu/g) ≤ 30 Blood penetration (kPa) ⩾ 16 (120mmhg)	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
5.2.4	Splash resistance 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.		P
5.2.5	Microbial cleanliness (Bioburden) When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1). NOTE EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation 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, follow the procedure below: The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.		P
5.2.6	Biocompatibility According to the definition and classification in EN ISO 10993-1, 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 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. As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.		P

EN 14683:2019			
Clause	Requirement – Test	Result - Remark	Verdict
6	Labelling and information to be supplied		P
	The following information shall be supplied in addition: a) number of this European Standard; b) type of mask (as indicated in Table 1).		P
Annex A	Information for users		P
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
Annex B	Method for in-vitro determination of bacterial filtration efficiency (BFE)		P

Attachments: real photos

Photo 1

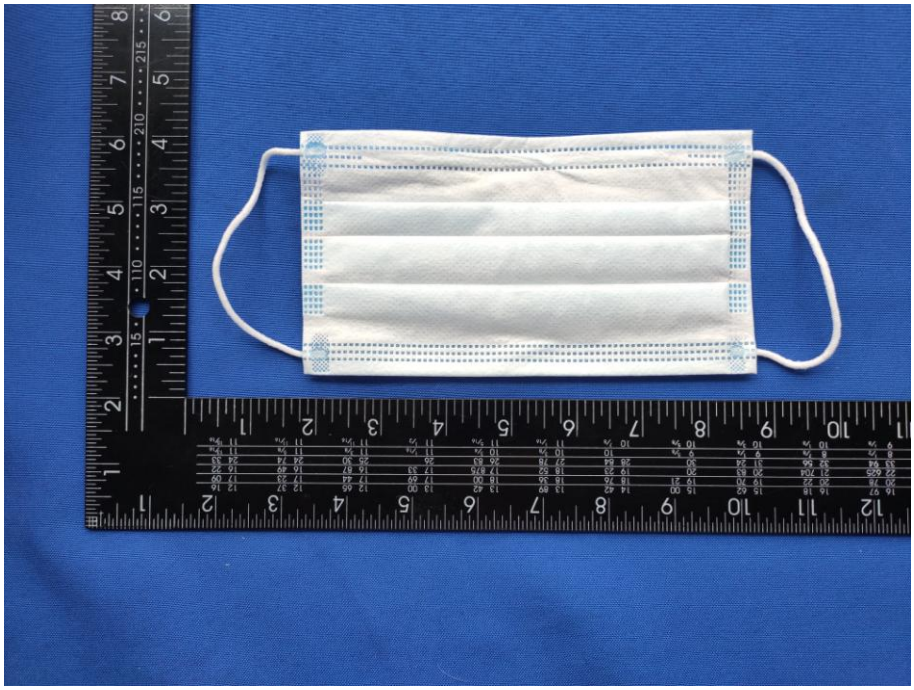

Photo 2

********** END OF THE REPORT **********