TEFANESO SERVICE

UNDER THE AUTORITY OF TEFANESO SWITZERLAND S. A.

3PLY PROTECTIVE FACE MASKS

CE and FDA certified

DISPOSABLE FACE MASK

- Latex-free and hypo-allergenic
- Pleated with ear loops
- Bacterial Filteration Efficiency
- Low breathing resistance
- 3-ply construction
- Soft inner surface for comfort
- Adjustable nose clip

APPLICATIONS

- Civil
- Industrial

Ref. 100 - 010
Ref. 100 - 011 (sterile)

TEFANESO SERVICES
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IDE: CHE-274.734.952

TEST REPORT

EN 14683:2005

Surgical masks — Requirements and test methods

EN ISO 10993-1:2009

Biological evaluation of medical devices –

Part 1: Evaluation and testing within a risk management process

Tested by (+ signature)	Wen Wei
Checked by (+ signature)	Apple Li
Approved by (+ signature)	Christina Deng
Date of issue	2020-03-15
Testing Laboratory Name	Shenzhen BST Technology Co., Ltd.
Address	Building No.23-24, Zhiheng Industrial Park, Guankou 2nd Road, Nantou, Nanshan District, Shenzhen, Guangdong, China
Testing location	CBTL ☐ CCATL ☐ SMT ☐ TMP ☐
Address	Same as above.
Standard	EN 14683:2005 EN ISO 10993-1:2009
Test procedure	Commissioned inspection
Test item description	Single-use medical face mask
Trademark	TIDELYCRA
Model and/or type reference	17.5×9.5cm

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.....: 2020-03-07

Date(s) of performance of test .....: 2020-03-07 to 2020-03-15

General remarks:

"(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.

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

EN 14683:2005

Clause	Requirement - Test	Result - Remark	Verdict
5	Requirements		P
5.1	General		-
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 (absence of particulate matter).		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, if applicable in their sterile state.		P
5.2.2	Bacterial filtration efficiency (BFE)		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.		P
5.2.3	Breathability		P

EN 14683:2005

Clause	Requirement - Test	Result - Remark	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.		P
5.2.4	Splash resistance		P
	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)		P
	When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1).		P
	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
	Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).		P
	The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.		P
	The total bioburden is expressed by addition of the TSA and SDA counts.		P
5.2.6	Biocompatibility		P

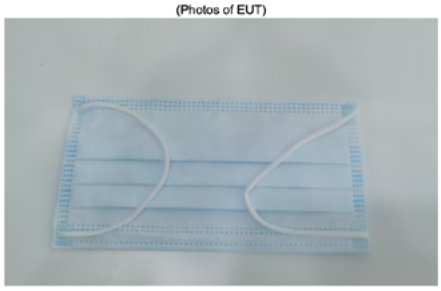
EN 14683:2005			
Clause	Requirement - Test	Result - Remark	Verdict
	According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine 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.		P
	As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.		P
5.2.7	Summary of performance requirements		P
6	Labelling and information to be supplied		P
	Annex I, §13. of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the medical face mask is 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
	N ISO 15223-1 and EN 1041 should be considered.		P
Annex B	Method for in-vitro determination of bacterial filtration efficiency (BFE)		P
Annex C	Method for determination of breathability (differential pressure)		P

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)	< 29,4	< 29,4	< 49,0
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.

APPENDIX
(Photos of EUT)



===End of report===

LIANTAN INDUSTRIAL No.95 OF LUOHU
SHENZHEN CHINA.
Website:WWW.RONGBIAOTEST.COM

RBT

Certificate of Conformity

No: RBT200318293SC-1

The following product has been tested by us with the listed standards and found in conformity with the council REGULATION (EU) 2017/745. It is possible to use CE marking to demonstrate the conformity with this MDR Directive.

EUT : Single-use medical face mask

M/N : 17.5×9.5cm

Test Standards : EN 14683:2019
EN ISO 10993-1:2009+AC:2010

CE

(Manager)

Mar. 18, 2020

The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the products same as the tested sample above mentioned only.

TEFANESO Services provide:

- Product sourcing,
- Quality control according to internal requirements,
- Order tracking,
- Support and assistance with customs and export formalities,
- Active search for solutions.

Our offices in Shanghai and Guangdong are located near the customs offices of these economic hubs. We are therefore able to intervene actively in the progress of customs formalities and procedures and thus help to speed up the finalization, if necessary.

TEFANESO Switzerland SA (hereinafter «Tefaneso») reserves the right to procure the product from supplier(s) different from the company indicated on the certificates mentioned in the appendix if such company cannot deliver the product. Tefaneso shall guarantee that the products from the other supplier(s) will scrupulously correspond to the product in terms of specifications, standards, tests and certifications.

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