Mascherine Chirurgiche medicali

DIVISIONE SICUREZZA

Mascherina	Mascherina chirurgica		
Confezione:	scatola 50 pz	Cartone:	3000pz
Colore	celeste		
Fissaggio	elastico spandex doppio		
Ponte nasale	alluminio malleabile		

Normativa **EN 14683:2019+AC:2019**
EN ISO 10993-1:2009

Caratteristiche	**Standard**	
Bacterial filtration effeciency (BFE)	> 95	✓
Differential pressure (Pa/cm²)	< 29,4	✓
Microbial cleanliness (cfu/g)	< 30	✓

I diversi tipi di mascherine

Veniamo all'ultimo capitolo, quello dell'efficacia. Non tutte le mascherine, infatti proteggono allo stesso modo. Ci sono diversi tipi di mascherine, che garantiscono vari gradi di protezione. In generale possiamo dire che le mascherine di tipo chirurgico, proteggono gli altri dalle secrezioni di chi le indossa e non viceversa, mentre quelle filtranti (con le dovute differenze), agiscono al contrario, proteggendo chi le indossa da agenti esterni pericolosi, virus e non solo.

Mascherine semplici, a uso igienico, adottate in alcuni contesti aziendali/industriali. Si tratta di prodotti generici, non pensati per l'utilizzo sanitario. Per questo motivo non devono rispettare le norme che invece le altre tipologie (le mascherine chirurgiche e i filtranti facciali) devono rispettare. Non necessitano di marcatura CE.

Mascherine chirurgiche (per uso medico). Sono quelle mascherine rettangolari fatte di tre strati di tessuto-non-tessuto plissettato che si indossano sul volto grazie a un nasello, elastici o lacci. Devono soddisfare alcuni requisiti tecnici stabiliti per legge e passare alcuni test specifici che verificano se la mascherina blocca le goccioline contaminate da batteri. Devono avere il marchio CE. Attenzione: il decreto Cura Italia ha introdotto alcune deroghe temporanee alla normativa per aumentare la disponibilità di questi prodotti. Attualmente si possono vendere legalmente, anche nelle farmacie, prodotti che vengono autocertificati dai produttori ma che non hanno seguito l'iter ufficiale dei test. Una cosa vale sempre, per entrambi i dispositivi, che siano certificati o autocertificati: per come sono pensate, questo tipo di mascherine non proteggono chi le indossa, ma le altre persone.

Maschere filtranti, dette anche filtranti facciali per la protezione individuale (da cui FFP). Si chiamano filtranti perché sono mascherine che sono realizzate in modo da bloccare il passaggio di particelle di dimensioni estremamente piccole, dell'ordine del mezzo micron, impedendo a chi le porta di inalarle. Sono dispositivi che bloccano a tutti gli effetti eventuali aerosol infetti da virus, ma anche fumi pericolosi, fibre e polveri. Queste FFP sono i veri e propri dispositivi di protezione individuale e infatti devono rispettare una normativa rigorosa. Queste mascherine hanno l'obbligo di marcatura CE e di riportare oltre al maschio CE anche il codice di quattro cifre che individua l'ente notificatore. L'efficacia filtrante viene indicata con sigle FF da P1 a P3 a seconda della capacità crescente di protezione. In ambito sanitario vengono usate le FFP2 e 3, che hanno un'efficacia filtrante rispettivamente del 94% e del 99% e sono le più indicate per bloccare i virus. La capacità filtrante della mascherina non è però infinita: dopo qualche ora di utilizzo il tessuto perde di efficacia, anche se la capacità filtrante non si annulla del tutto. Se sono monouso, queste maschere vanno gettate dopo un turno di utilizzo o dopo un determinato numero di ore. Questi dispositivi possono avere anche una valvola di espirazione (che facilita la vita a chi la usa in ambito medico). In questo caso però proteggono chi le indossa ma non viceversa, perché l'esalazione non è filtrata. Per questo motivo le maschere filtranti facciali con valvola sono da destinarsi all'uso sanitario nei reparti dove sono ricoverati casi infetti per la protezione degli operatori. Esistono anche FFP senza valvola.

Come Indossare:

Review Report –审查报告–검토 보고서– Rapport d'Evaluation

CE Documentation Review

No. OP200324S.FGM0T22

Holder: Fujian Guardian Medical Technology Co., Ltd
Xingdong Industrial Zone, Dongyuan Town, Quanzhou Taishang Investment Zone,
Fujian Province, China (No.3 Factory of tuopuke (China) Co., Ltd.)

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Medical Mask (Not Sterile)

Model(s): 14.5CM*9CM, 15.5CM*10.5CM, 17.5CM*9.5CM

Classification: Class I (Not Sterile)
(accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.
Technical documentation identified with the no. TMGD20032023093 dated 24 march.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 24 March 2020
Approver
ECM Service Director
Luca Bedonni

Expiry date 23 March 2025

Technical Expert
Amanda Pagnin

CERTIFICATION EUROPE HONG KONG

认证证书

医疗器械管理体系

证书编号：10136664M

兹证明

福建盖迪恩医疗科技有限公司

福建省泉州台商投资区东园镇杏东片区工业启动区
（拓浦柯（中国）有限公司三号厂房3楼

医疗器械质量管理体系认证符合标准

ISO13485:2016

医疗器械质量管理体系适用于

第一类医疗器械、第二类医疗器械、第三类医疗器械、
非医用日用防护口罩、医用防护口罩生产

发证日期：2020-03-26　　证书有效期至：2023-03-25

获证组织在证书有效期内每年至少接受一次监督审核，并将监督审核合格标识粘贴于证书指定位置，证书方为有效。

IAF　UKAS QUALITY MANAGEMENT 0219

签发：Framco

12个月	24个月

欧洲认证（香港）有限公司　　WWW.CCE-HK.COM

PAGINA 7

CERTIFICATION EUROPE HONG KONG

Certificate of Registration

Medical Device Management

Certificate NO：10136664M

This is to Certify that the Medical Devices Industry Management System of

Fujian Guardian Medical Technology Co., Ltd.

3/F, Building 3, Industrial Start up Area (Tuopuke (China) Co., Ltd.)
Xingdong Zone, Dongyuan Town, Taizhou, Fujian Province, China

Has been audited to the following Medical Devices Industry Management System standard:

ISO13485:2016

This system is valid for the

Production of class I medical devices, class II medical devices, class III medical devices, non-medical daily protective masks and medical protective masks

Date of issue: Mar. 26, 2020　　**Date of expiry: Mar. 25, 2023**

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit conforming mark is in the designated position on the certificate.

IAF　UKAS QUALITY MANAGEMENT 0219

Issued by: Framco

12months	24months

CERTIFICATION EUROPE(HONGKONG)LIMITED　WWW.CCE-HK.COM

PAGINA 8

TEST REPORT

EN 14683:2019+AC:2019

Medical face 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	Wenwei
Checked by (+ signature)	Apple Li	Apple Li
Approved by (+ signature)	Christina Deng	
Date of issue	2020-03-23	

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.

Applicant's Name	Fujian Guardian Medical Technology CO.,Ltd
Address	Xingdong Industrial zone, Dongyuan Town, Quanzhou Taishang Investment Zone,Fujian Province China(No.3 Factory of tuopuke (China)Co.,Ltd)
Standard	EN 14683:2019+AC:2019 EN ISO 10993-1:2009
Test procedure	Commissioned inspection
Procedure deviation	N/A.
Test item description	Disposable Medical Mask(Not Sterile)
Manufacturer	Fujian Guardian Medical Technology CO.,Ltd
Address	Xingdong Industrial zone, Dongyuan Town, Quanzhou Taishang Investment Zone,Fujian Province China(No.3 Factory of tuopuke (China)Co.,Ltd)
Trademark	N/A
Model and/or type reference	17.5CM*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.....: 2020-03-17
Date(s) of performance of test .....: 2020-03-17 to 2020-03-23

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

Label:

Note: Due to similarity of the rating labels, only above label is listed

EN 14683:2019+AC:2019			
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 14683:2019+AC:2019			
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 14683:2019+AC:2019			
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

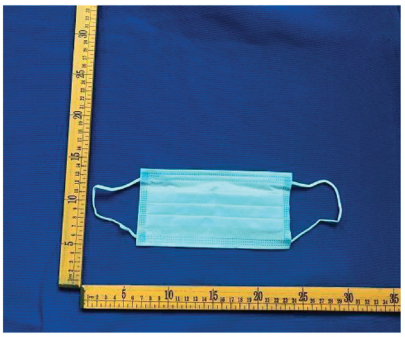
Annex C	Method for determination of breathability (differential pressure)		P

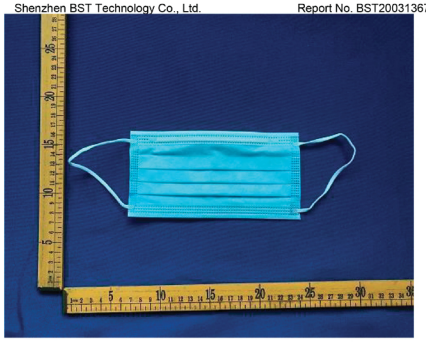
Table 1 — Performance requirements for medical face masks

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===

Salbaroli sas
Via gamba, 16 Ravenna
Tel. 054432032 mail: salbaroli@salbaroli.it

SCHEDA D'ORDINE

da compilare e restituire via e-mail a salbaroli@salbaroli.it

Il sottoscritto _____

In qualità di legale rappresentante dell'azienda: _____

con sede a _____

telefono _____ e-mail _____ Partita IVA _____

codice univoco _____

Indirizzo di spedizione, se diverso dalla sede legale

_____

Sottopone la propria richiesta di sottoscrizione del seguente articolo:

SCHEDA D'ORDINE MASCHERINE MONOUSO				
ARTICOLO	**QUANTITA'**	**IMPORTO**		
Descrizione	N.	Unitario	Totale imponibile	+Iva 22% Totale Fattura
Mascherine chirurgiche medicali	100 o multipli	€ 1,10		
Spese di trasporto	Fuori dal comune di RA	€ 15,00		€ 18,30

Disponibilità immediata fino esaurimento scorte

Pagamenti:

- Anticipato alla firma della presente scheda d'ordine
- Causale: Conferma d'ordine Nome dell'Azienda
- Inviare la distinta di pagamento a salbaroli@salbaroli.it

C/C IBAN: IT29V0538713120000000008085 Banca Popolare dell'Emilia Romagna intestato a Cartolibreria Salbaroli s.a.s.

Data: _____

Timbro e firma del legale rappresentante: _____