PROTECTHOMS
Distributeur d'Excellence

REFERENCE : 1MA050181

DESIGNATION : MASQUE CHIRUGICAL 3 PLIS TYPE 2

NORMES : EN14683

>> Caractéristiques techniques

Modèle: Masque chirurgical de type II . Constitué de trois couches de polypropylène en non-tissé. Deux couches extérieures spunbond et une couche intérieure meltblown constitue le matériau filtrant. Chaque côté du masque dispose d'un élastique permettant la fixation du masque sur le visage.
Une barrette nasale métallique et recouverte de plastique permet d'ajuster le masque sur le visage au niveau du nez

Matières et coloris: - En polypropylène. - Elastique de fixation

Boite de 50 pièces

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OCT
OUCHENG TESTING

Certificate of Conformity

Certification No:	**OCT20200319809M**
Applicant:	**Shenzhen missadola technology co.,ltd.**
Address:	**602# longyuan building industry road minzhi street longhua xinqudistrict shenzhen city China**
Manufacturer:	**Shenzhen missadola technology co.,ltd.**
Address:	**602# longyuan building industry road minzhi street longhua xinqudistrict shenzhen city China**
Certification Marking:	**CE-MDD**
Product Description:	**Disposable Medical face mask**
Model:	**17.5cm*9.5cm**

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards	:	**EN 14683:2005**

When tested as specified, the submitted sample complies with 93/42/EEC (Medical Devices)

The certificate is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test laboratory logo.

CE

Authorized Signer:

Mar 19, 2020

Oct Technology Testing Co., Ltd.

637,No. 56, zhongyun Road,Panyu District,Guangzhou,Guangdong Province,China
TEL:020-89015652,888@oucetesting.com,www.oucetesting.com

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Test Report No.:OCT20200319809M

MDD TEST REPORT

Applicant:	Shenzhen missadola technology co.,ltd.
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Manufacturer:	Shenzhen missadola technology co.,ltd.
Address:	602# longyuan building industry road minzhi street longhua xinqudistrict shenzhen city China
Product:	Disposable Medical face mask
Model:	17.5cm*9.5cm
Test standard:	EN 14683:2019
Conclusion:	The product tested conforms to the standards listed above.
Test date:	2020,3.15-3.19
Issue date:	2020,3.19
Reviewed by:	
Approved by :	
Prepared by:	

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Notice

1. This test report shall be invalidation without the cachet of the testing laboratory.

2. This copied report shall be invalidation without sealed the cachet of the testing laboratory.

3. This report shall be invalidation without tester signature, reviewer signature and approver signature.

4. This altered report shall be invalidation.

5. Client shall put forward demurrer within 15days after received report. The testing laboratory shall refuse disposal if exceeded the time limit.

6. The test results presented in this report relate only to the object tested.

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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 I	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.	Meet the requirements	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.	The wire holds the shape and makes the mask fit tightly to the nose	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)		N
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	All tests shall be carried out on finished products or samples cut from finished products.		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	See table 1.	P

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	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		P
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.		P
5.2.3	Breathability		P
	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
	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
5.2.4	Splash resistance		N
	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
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).	1#: 27.4 CFU/g; 2#: 27.3 CFU/g; 3#: 27.3 CFU/g; 4#: 27.2 CFU/g 5#: 27.4 CFU/g	P
	NOTE EN ISO 11737-1:2018 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.		P
	To determine the mask' s bioburden according		P

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	to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.		
	The number of masks that shall be tested is minimum 5 of the same batch/lot.		P
	Other test conditions as described in EN ISO 11737-1:2018 may be applied.		P
	In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.	27.32	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

6	Marking, labelling and packaging		P
	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.		P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN 14683:2019	P
	b) type of mask (as indicated in Table 1).	Type I a	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

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Table 1 — Performance requirements for medical face masks

Table 1	The performance test			Result
Test	Type I a	Type II	Type IIR	Type I a
Bacterial filtration efficiency (BFE), (%)	≥95	≥98	≥98	97.1
Differential pressure (Pa/cm 2)	<40	<40	<60	35.6
Splash resistance pressure (kPa)	Not required	Not required	≥16,0	--
Microbial cleanliness (cfu/g)	≤30	≤30	≤30	27.32
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.				

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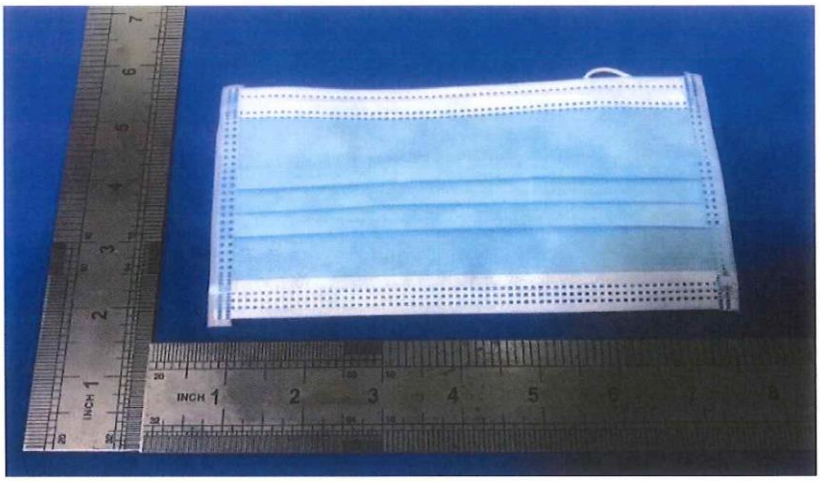
Photo of the sample



*** End of report

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