Eldobható szájmaszk





Multi-layer protection



Skin affinity



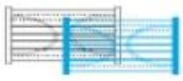
Human face design



Easy to use



Packaging can be customized



Multicolor optional

1.Jellemzők:

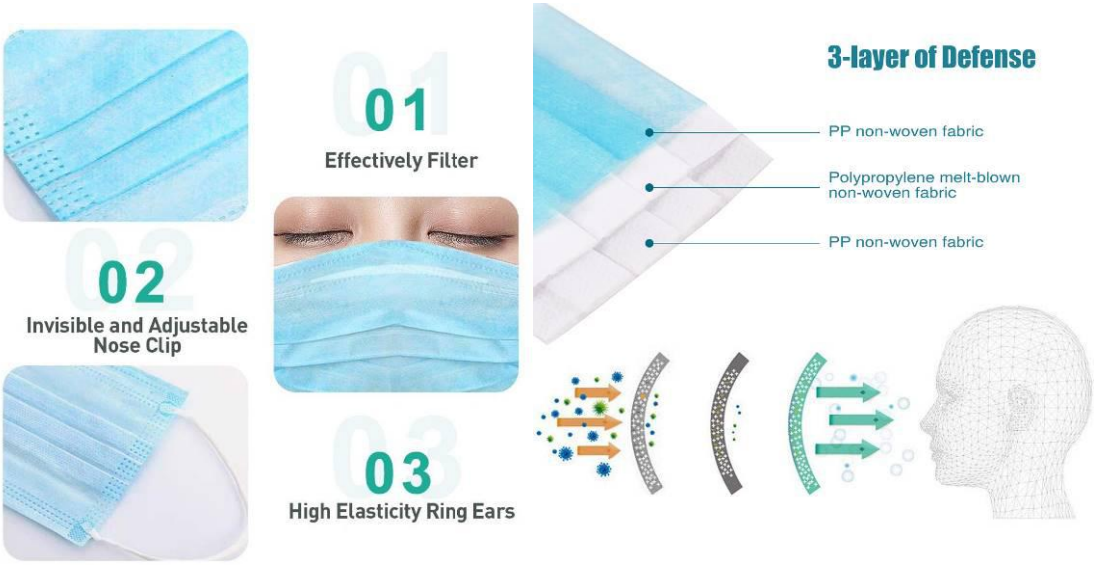
1, Anyag: Nem szövött Polipropilén
2, Méret: 17,5x9,3cm, 17,5x9,5cm, vásárló igénye szerint.
3, Szín: Fehér, zöld, kék, rózsaszín, sárga, szürke (további színek is elérhetők).
4, Stílus: Elasztikus fülpántos.
5, Réteg: Általában 3, 2 és 4 rétegű.
6, Orrnyereg: 1 vagy 2 alumínium csíkkal
7, Gazdaságos, könnyű, Nem irritáló, Kényelmes
8. Megvéd a baktériumoktól, portól vagy köhögéstől

1). A szűrőmaszkok csökkentik az influenza átterjedő vírusokat és baktériumokat, és megakadályozzák barátait, családtagjait és másokát a hidegtől.
Filter masks help reduce the viruses and bacteria that transmit the flu and keep your friends, family and others from contracting the cold.





2. The product uses non-woven fabrics such as ultrasonic heating, spot welding and tape production processes, cellulose and paper / co-carbon steel aseptic for single use. Dustproof, breathable, hypoallergenic and sterilized. They block dust and microorganisms without causing stress or anaphylactic reactions to last through. The smooth fabric uses reduced fabric falloff wash-free maintenance-free, convenient, practical, safer and healthier.



Műszaki adatok:

Termék	BFE99 Meltblown Cloth Antibacterial
Anyaga	Non-woven fabric
Végrehajtási előírások	YYKZ20200201
Garancia	9.5*17.5cm
Garancia	1year
Tárolási követelmények	relative humidity not exceeding 80% non-corrosive gas and Well-ventilated room to avoid high temperature;
Kiszerelés	50pcs
Szállítási idő	according to the order qty),normally are in stock.

3. Csomagok: **Packages Can Be Customized**

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0P200310.HET0O40

Technical Construction File no. TPHN20030921990

Certificate's Holder:	Hunan Jinhai Medical Equipment Co., Ltd. No.203, A1 E Center, 8 Xiangtai Road, Liuyang Economic Development, Hunan Province
Certification ECM Mark:	Type Approved
Product:	Disposable face mask
Model(s):	YX001, YX002, YX005, YX007, YX9001, YX9501
Verification to:	Standard: EN 149: 2001+A1:2009 related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:

We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE *Marking Certification Procedure* through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 10 March 2020

Chief Manager
Mirco Morini

Expiry date 09 March 2025

Deputy Manager
Amanda Payne

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TEST REPORT

Report No : CMAT2020031901C Date: Mar.19,2020 Page: 1 of 6

Applicant	:	Hunan Jinhai Medical Equipment Co.,Ltd
Address	:	203#, Building A1, Changsha E center,18 XiangTai Rd., Economic & Technical development park, Liuyang, Hunan,China
Manufacturer	:	Hunan Jinhai Medical Equipment Co.,Ltd
Address	:	203#, Building A1, Changsha E center,18 XiangTai Rd., Economic & Technical development park, Liuyang, Hunan,China

The following samples were submitted and identified by/on behalf of the client as:

Sample Name	:	Medical mask
Brand:	:	/
Sample Model	:	PM-G-D-D（asepsis）,PM-G-D-DF(Non-sterile)，PM-G-D-S（asepsis）, PM-G-D-SF（Non-sterile），KN95ar-loop face mask / medium size
Model May Cover	:	/
Sample Received Date	:	Mar.10,2020
Testing Period	:	Mar.11,2020~ Mar.19,2020
Test Method	:	EN 14683:2019 Medical face masks–Requirements and test methods Medical devices Directive 93/42/EEC
Test Result	:	Tests requested in accordance to client requirement

Note: 1.The ambient temperature of the test environment：22°C

Report compiled: Yan Luo **Report issued:** Zilu Jian **Report date:** Mar.19.2020

Yan Luo / File administrators **Zilu Jian / Technique principal**



TEST REPORT

Test result:

EN 14683			
Clause	Requirement- Test	Result-Remark	Verdict
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. The 'R' signifies splash resistance.	Type Ia	Pass
5	Requirements		/
5.1	General	/	Pass
5.1.1	Materials and construction The mical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulbetween 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	According to the documents provided by the manufacturer and visual inspection, judged to meet the clause of the standard	Pass
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 face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, ora nose bridge (to enhance fit by conforming to the nose contours).	According to the documents provided by the manufacturer and visual inspection, judged to meet the clause of the standard	Pass
5.2	Performance requirements	Meet the requirements	Pass

TEST REPORT

5.2.1	General All tests shall be carried out on finished products or samples cut from finished products.	/	/
5.2.2	Bacterial filtration efficiency (BFE) 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. For thick and rigid masks such as rigid duckbill or cup masks the test	BFE：95%	Pass
	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. When a mask consists of two or more areas with different characteristics or different layer- composition, each panel or area shall btested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.		
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. 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)	Differential pressure：39Pa/cm^2	Pass
5.2.4	Splash resistance 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.	Not required	Pass

TEST REPORT

5.2.5	Microbial cleanliness (Bioburden) When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1). To determine the mask's bioburden according 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. Other test conditions as described in EN ISO 11737-1:2018 may be applied. In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.	Microbial cleanliness:30 cfu/g	Pass
5.2.6	Biocompatibility 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 comlete 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.	/	/
5.2.7	Summary of performance requirements	/	/

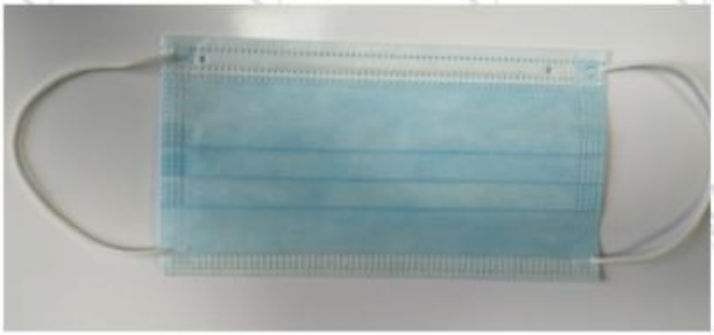
	Table 1 — Performance requirements for medical face masks (see table below)		
6	Marking, labelling and packaging		Pass
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied: a) number of this European Standard; b) b) type of mask (as indicated in Table 1). c) EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	According to the documents provided by the manufacturer and visual inspection, judged to meet the clause of the standard	Pass

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
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.

TEST REPORT

Sample image:



---------- End of Report----------

CMAT