

Medizinische Maske EN 14683 Typ I

Produktinformation medizinische Maske

- Medizinische Maske Typ I gemäß EN14683
- BFE (Bakterienfiltereffizienz) > 99%
- PFE (Submicron Particulate Filtration Efficiency @0.1 micro) > 95%
- Sehr leichte, 3-lagige Qualität
- Bequemer Sitz: integrierter, individueller anpassbarer Nasenbügel
- Vollkommen unbehinderte Atmung
- Für den Einmalgebrauch, nicht für den OP - Gebrauch geeignet

Abmessungen

95mm x 175mm +/-10mm

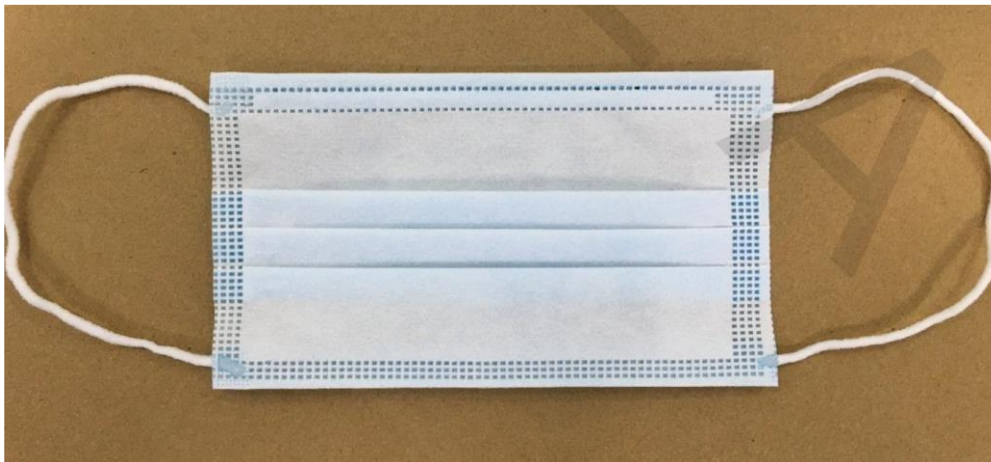
Verpackungseinheit: 10 Stück

Farbe: Blau

Vorderseite



Rückseite



Wagner Technik GmbH

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Geschäftsführer Wei Chen – Handelsregister Wuppertal HRB 20157

BW Bank IBAN DE67 6005 0101 7401 5112 94 BIC SOLADEST600

Ust. IdNr. DE255841234 Steuernummer: 131/5916/0823 FA Wuppertal Barmen



Verpackungseinheit: 10 Stück



Confirmation of EU product notification

Herewith we confirm that

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

has taken over the function of an European Authorised Representative according to the requirements of Regulation 2017/745(EU) for:

Hygea Medical Technology Co., Ltd.
101-1102, 1/F, Building No. 2, No. 103 Beiqing Road
Haidian District, Beijing, P.R. China

for their medical devices:

Disposable Medical Face Mask (Class I)

and has submitted the product notification at the relevant German Competent Authority according to Article 29 and Article 31 of the above mentioned Medical Device Regulation and all supporting technical documentation showing the devices' conformity with the Regulation is deposited in our office.

12 March 2020

Shanghai International
Holding Corporation
GmbH (Europe)
Eiffestraße 80
20537 Hamburg



Mr. Jin Liang
-- on behalf of --
Shanghai International Holding
Corp. GmbH (Europe)

Inspection Report

Report number:Z-Y-0091-2020

Product code/ Batch No:2003001

No	Inspection items	standard clauses	Requirement	Result of inspection	Single conclusion	
1	Appearance	2.1	The appearance shall be clean and in good shape, and the surface shall be free of damage and stain.	Meet the requirements	Confirmed	
2	Structure and dimensions	2.2	After wearing, it shall be able to cover the nose, mouth and jaw of the wearer, and shall conform to the design in annex A and table A-1 of technical requirements for disposable surgical mask of Hygea Medical Technology Co.,Ltd.	Meet the requirements	Confirmed	
			Length L	175mm ±10 mm	Maximum deviation: +1.0mm	Confirmed
			Width W	95mm ±10mm	Maximum deviation: +1.0mm	Confirmed
3	Nose piece	2.3.1	The mask shall be equipped with a nose clip made of plastic material.	Meet the requirements	Confirmed	
		2.3.2	The length of nose clip shall not be less than 8.0cm.	Minimum value: 11.1cm	Confirmed	
4	Ear loops	2.4.1	The ear loops should be easy to wear.	Meet the requirements	Confirmed	
		2.4.2	The breaking strength at the connection point between each ear loop and the mask body shall not be less than 10N.	>10N	Confirmed	
5	Synthetic blood penetration	2.5	After 2ml synthetic blood is sprayed to the outer layer of the mask at a pressure of 16.0kpa (120 mm Hg), there should be no penetration on the inner layer of the mask.	Not penetrated	Confirmed	
6	Bacterial filtration	2.6.1	The bacterial filtration efficiency of the product shall not be less	Minimum value:99.9%	Confirmed	

Beijing Medical Device Quality Supervision Co., Ltd. of China Food and Drug Administration

	efficiency (BFE)		than 95%.			
7	Particle filtration efficiency (PFE)	2.6.2	The filtration efficiency of the product for non oil particles shall not be less than 30%.	Minimum value 95.6%	Confirmed	
8	Pressure difference (ΔP)	2.7	The pressure difference Δp between the two sides of the product for gas exchange shall not be greater than 49 Pa.	Maximum value: 33.0Pa	Confirmed	
9	Flame resistance	2.8	The product material shall be nonflammable; the burning time of the mask after leaving the flame shall not be more than 5S.	0S	Confirmed	
10	Microbial index	2.9	The microbial index of the product shall meet the requirements of Table 2 of technical requirements for disposable surgical mask of Hygea Medical Technology Co.,Ltd.	< 20 cfu/g	Confirmed	
			Total bacterial colony cfu / g			≤ 100
			Coliform group	Cannot be checked out	Not checked out	Confirmed
			Pseudomonas aeruginosa	Cannot be checked out	Not checked out	Confirmed
			Staphylococcus aureus	Cannot be checked out	Not checked out	Confirmed
			Hemolytic streptococcus	Cannot be checked out	Not checked out	Confirmed
			Fungus	Cannot be checked out	Not checked out	Confirmed