50 Stück Kinder OP-Masken 3-lagig EN14683 CE MNS Einweg

Björn&Schiller

Artikelnummer: **8407**

CE Zertifizierung:

Geprüft und CE-zertifiziert gemäß der Norm EN 14683:2019 Type IIR - Hochgradiger Filterleistung ≥ 98%.

Eigenschaften:

- TYP: Kindergesichtsmasken für Kinder ab 3 bis ca. 12 Jahren
- EFFIZIENTES 3-SCHICHT FILTERSYSTEM: Farbige Vliesschicht blockt sichtbare Partikel effektiv. Die Meltblown Schicht filtriert Partikel und nichtölhaltige Aerosole ebenfalls effizient aus der Luft und innere Vliesschicht nimmt heiße und feuchte Luft auf und lässt die Haut trocken bleiben.
- PERFEKTE PASSFORM: Einwegmasken passen sehr gut für Kinder ab 3 bis ca. 12 Jahren dank der angepassten Größe von 14,5 cm x 9,5 cm (± 0,5 cm).
- VIELFÄLTIGE ANWENDUNG: Die Masken können im Alltag, in der Schulen und KITAs, sowie auch im Medizinbereich verwendet werden.
- MATERIALIEN: Vliesstoff
- HALTBARKEIT: 2 Jahre (Herstellungsdatum auf der Verpackung)

Packungsinhalt:

50 Stück Mund-Nasen-Schutzmasken für Kinder pro Box

Die Kinder OP-Masken jetzt bestellen:
https://www.westandeast.de/index.php?a=7715
oder hier klicken.

WEST & EAST GmbH | Vahrenwalder Str. 213 | D-30165 Hannover
Tel: 0511 5151 4030 | E-Mail: info@westandeast.de | Website: www.westandeast.de oder www.bjoernschiller.de

EC Declaration of Conformity

Manufacturer:

Hangzhou Shiwang Clothing Co., Ltd
Building 2, No.58 Wuqiang Road, Fenkou Town,
Chun 'an County, Hangzhou City, Zhejiang
Province, China

whose single Authorized EU-Representative:

M/s CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga,
Spain

We, the manufacturer, herewith declare that the products

Disposable Medical Mask *(KID)*
Model: Ear-Loop
Classification mask: Type I, Type II, Type IIR
EN14683:2019 + AC:2019

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Hangzhou Shiwang Clothing Co., Ltd
Building 2, No.58 Wuqiang Road, Fenkou Town, Chun 'an County, Hangzhou City, Zhejiang Province, China

签字盖章

Hangzhou 2020/10/15
Place, date

Zhiye Lu
Legally binding signature, Function

Date:2020/10/15

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/16062020.7

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Hangzhou Shiwang Clothing Co., Ltd
58 Wuqiang Road, Fenkou Town, Chun'an County, Hangzhou City,
Zhejiang Province, China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1427/2020**

CE

Issued on: 16/06/2020

Valid until: 15/06/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Disposable Mask

CE

HANGZHOU SHIWANG CLOTHING CO., LTD
58 WUQIANG ROAD, FENKOU TOWN, CHUN'AN COUNTY, HANGZHOU CITY, ZHEJIANG PROVINCE

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Disposable Medical Mask (KID)
SGS Internal Ref.No.	:	NBHL2011500029MD
Sample Color	:	(A)blue
Style No.	:	Ear-Loop Specification: 14.5*9.5cm
Lot No.	:	20201101
Manufacturer	:	HANGZHOU SHIWANG CLOTHING CO., LTD
Country of Origin	:	China
Country of Destination	:	EUR
Other Info.	:	Brand Name: CNQYJY, Production Date: 2020.11.01
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Nov 06, 2020
Testing Period	:	Nov 06, 2020 - Nov 18, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~146mm x 162mm
Positive Control Average	:	2764 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	22.9	25
	1-2	23.6	
	1-3	25.0	
	1-4	28.3	
	1-5	25.5	
2	2-1	22.3	23
	2-2	22.6	
	2-3	22.8	
	2-4	25.4	
	2-5	23.3	
3	3-1	26.0	25
	3-2	21.3	
	3-3	22.7	
	3-4	27.6	
	3-5	27.0	
4	4-1	22.1	24
	4-2	21.6	
	4-3	26.0	
	4-4	23.9	
	4-5	27.1	
5	5-1	25.0	25
	5-2	24.8	
	5-3	24.1	
	5-4	23.7	
	5-5	25.9	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

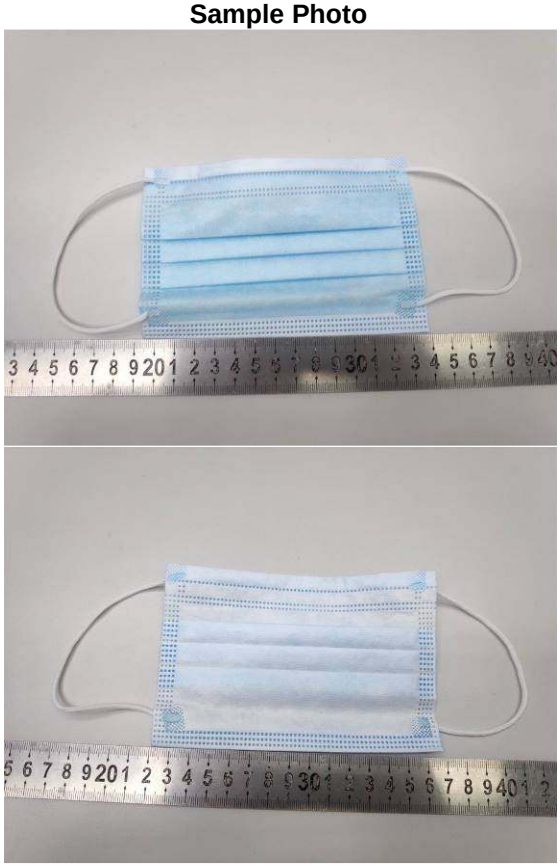
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.36	3	0.89
2#	3.38	<3	<0.89
3#	3.34	9	2.69
4#	3.31	3	0.91
5#	3.35	3	0.90

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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