

KATALOG JEDNORÁZOVÝCH ROUŠEK

EU05/04.10 –

Zdravotnické masky 3 layers – Nowoven Polypropylene /Meltblown/Nowoven Polypropylene Jednorázové použití.

- Bezpečná ochrana pro lékaře i pacienta před infekcí.

K ochraně uživatele před kapénkovou infekcí a zároveň minimalizují šíření infekce, pokud je uživatel nakažen.





CERTIFICATE OF COMPLIANCE

No.: CE202000160

Applicant: Shenzhen Huanuo Medical Equipment Co., Ltd
2nd floor, hezhengfeng building, zone 704 , bao'an airport, sanwei community, hangcheng street, bao'an district, shenzhen city.

Manufacturer: Shenzhen Huanuo Medical Equipment Co., Ltd
2nd floor, hezhengfeng building, zone 704 , bao'an airport, sanwei community, hangcheng street, bao'an district, shenzhen city.

Product: Child₁Protective Mask(Children/non-medical)

Trade Mark: /

Type/ Models: WR-1, WR-2, WR-3, WR-4, WR-5

EU directive(s): Personal Protective Equipment Regulation (EU) 2016/425

Standard(s): EN 149:2001+A1:2009

Remark: The certificate of compliance is based on the evaluation of sample(s) of the above mentioned product on a voluntary basis. This is to confirm that the tested sample(s) is in conformity with the EU directive(s). Therefore, it does not imply the assessment of the production of the product The applicant is authorized to use the certificate in connection with the EC Declaration of Conformity. This Certificate of Compliance can be checked for validity at: www.tuv-world.es

Date of issue: 27/03/2020

Date of expiry: 27/03/2025

Certification Manager: _____



TUV-WORLD ECC CERTIFICATION SERVICE,S.L.
ADDRESS:PS DE LA CASTELLANA 114, 28046-MADRID,SPAIN
TEL: + 34 912 127 295 E-MAIL: info@tuv-world.es

Certificate of Compliance



No. 2C200402M.GJ10W64

Certificate's Holder:

Shenzhen HUANUO MEDICAL EQUIPMENT CO.,LTD
2nd floor,hezhenfeng building,zone 704,bao'an airport,sanwei community,hangcheng street,bao'an district,shenzhen city.

Certification ECM Mark:



Product:

Protective Mask(Children/non-medical)

Model(s):

Verification to:

Standard:

EN 149:2001+A1:2009

related to CE Directive(s):

R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer, it is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. 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)

Issuance date: 02 April 2020

Expiry date: 01 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine Srl

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中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report **SL52025258596201TX** **Date: June 19, 2020** **Page 1 of 3**

Shenzhen HUANUO MEDICAL EQUIPMENT CO.,LTD

2nd floor, hezhengfeng building, zone704, baoan airport, sanwei community, hangcheng street, baoan district, shenzhen city

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

Sample Description : (A) Disposable respirator (Type II)

SGS Internal Ref No. : GZES2005018176ME

Style No. : HN02

Sample Color : (A) blue

Manufacturer : ShenZhen HUANUO MEDICAL EQUIPMENT CO.,LTD

Lot No./Batch No. : Not provided

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : May 25, 2020

Testing Period : May 26, 2020 - Jun 19, 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).

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods	(A)
Clause 5.2 Performance Requirement	
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	EXCLUDED
Clause 5.2.5 Microbial Cleanliness	M
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type II)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type II)

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

Sara Guo

Sara Guo (Account Executive)

Dongjing Liu Helen Xuan

Dongjing Liu / Hailian Xuan (Authorized Signatory)



SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd
Testing Center

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Member of the SGS Group (SGS SA)

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
 Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : 170 mm x 155 mm
 Test Area : ~60 cm²
 Test Side : Inside
 Flow Rate : 28.3 l/min
 Positive Control Average : 2.3 x 10³ CFU
 Negative Monitor Count : < 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.9	99.9	99.9	99.9

Remark: Performance Requirement: Type I ≥95%, Type II ≥98%, Type IIR ≥98%

Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A
 Test number and location : 5 random areas for each specimen (face mask)
 Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Area : 4.9 cm²
 Flow Rate : 8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm ²)	47	50	47	47	45

Remark: Performance Requirement: Type I <40 Pa/cm², Type II <40 Pa/cm², Type IIR <60 Pa/cm²

Clause 5.2.5 Microbial Cleanliness

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

	1#	2#	3#	4#	5#
CFU/g	10	3	4	2	8

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



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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

Společně bojeme proti kovidu !

