

# AB Tip İnceleme Sertifikası **EU Type-Examination Certificate**

Belge No / Certificate No

: 145-21-01-R01

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /

Certification Date / Certificate Validity Date

: 10.05.2021-03.02.2026

Belge Gecerlilik Tarihi / Document Validity Period: 5 yıl / 5 years

Firma Unvanı ve Adresi / Company Name and Address

: Maskenshop Berlin PSA GmbH

Köpenicker Str. 16-17, 10997 Berlin, Germany

Ürün Adı /Modeller / Product Name / Models

Direktifi / Directive

Modülü/Kategori / Module / Category

; XBRGwhite, XBRGblack, XBRGsmall

: 2016/425 REGULATION

: B MODÜLÜ/ KATEGORİ III MODULE B / CATEGORY III

: M-2021-00104, M-2021-00807

Test Rapor No/ları / Test Report No

Urün Tipi / Product Type:

- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ Respiratory protective devices - Filtering half masks to protect against particles

Ürünün Malzeme Bilgisi / Product Material Information: XBRGwhite, XBRGblack, XBRGsmall model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ XBRGwhite, XBRGblack, XBRGsmall model products are manufactured using fabric, elastic strap, nose clip, filter layer. Revizyon nedeni / Reason for revision: Farklı renk ve ebatta ürünler eklenmiştir./ Different color and size products have been added.

Volkan AKIN 10.05.2021 Karar Veridi / Amprover

Okan AKEL 10.05.2021 Şirket Müdürü / General manager



MNA Laboratuvarları San. Tic.Ltd .Şti Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com



# ATTACHMENTS (145-21-01-R01)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

Model: XBRGwhite, XBRGblack, XBRGsmall

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

#### MARKING

MANUFACTURER: Maskenshop Berlin PSA GmbH PPE TYPE:

EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles

MODEL: XBRGwhite, XBRGblack, XBRGsmall

PRODUCT SIZE: Large and Small

PICTOGRAM AND PERFORMANCE LEVELS:

EN 149:2001+ A1:2009 FFP2 NR

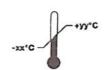
NB 2841











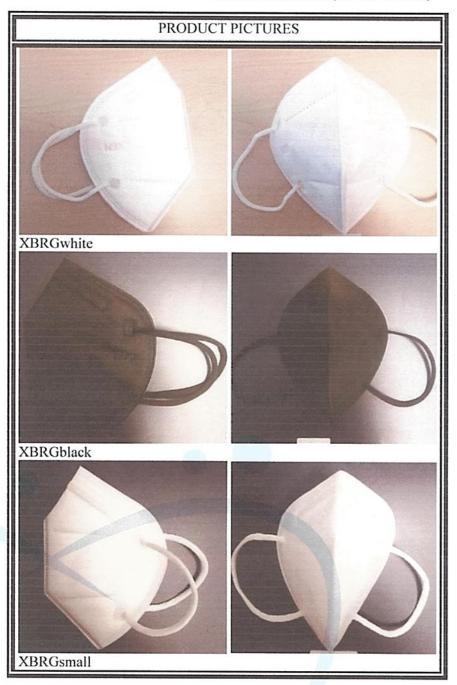


Or Condition of Storage

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.



# ATTACHMENTS (145-21-01-R01)



# DOCUMENTS IN THE TECHNICAL FILE

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report

MNA Laboratuvarları San. Tic.Ltd .Şti Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul Tel: 0216 574 07 08 Faks: 0216 575 13 31 <a href="www.mnalab.com">www.mnalab.com</a>



#### **TECHNICAL EVALUATION REPORT (145-21-01-R01)**

Report No

: 145-21-01-R01

**Report Date** 

: 10.05.2021

**Application No** 

: 145-21-01

#### 1. COMPANY INFORMATION:

Maskenshop Berlin PSA GmbH

Köpenicker Str. 16-17, 10997 Berlin, Germany

Tel: 0049 30 814 55 710

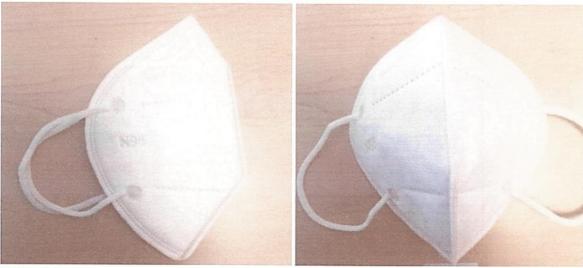
#### 2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection fitler material.

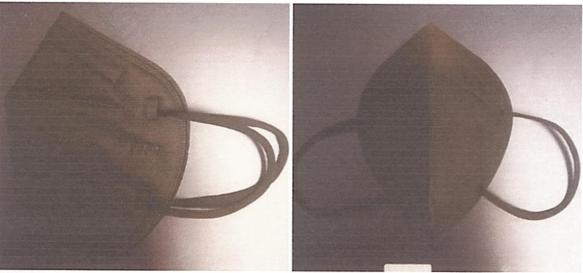
#### 3. PPE TYPE IDENTIFICATION

EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

#### 4. PPE PICTURES



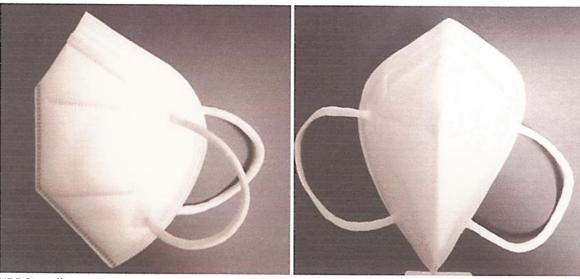
**XBRGwhite** 



**XBRGblack** 



#### **TECHNICAL EVALUATION REPORT (145-21-01-R01)**



**XBRGsmall** 

#### 5. PPE DIMENSIONS:

XBRGwhite, XBRGblack, XBRGsmall models have been found to be produced using large and small sizes.

## 6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and fitler material on the middle layer.

## 7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- A visual inspection was made according to EN 149:2001 +A1:2009 for ergonomics.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials were determined by visual inspection according to EN 149:2001 +A1:2009.

# 8. ANALYSIS AND EVALUATIONS: EN 149:2001 +A1:2009

TESTS	PARAMETER		RMANC	Œ	RESULTS	PERFORMANCE	EVALUATION
		FFP1	FFP1 FFP2 FFP3			LEVELS	
Part 7.3 Visual inspection	Shall also the markin supplied by the manuf	T-1		mation	Appropriate	-	PASS
Banned Azo Dyes	< 30 mg/kg	30 mg/kg				-	PASS
Part 7.4 Packaging	Particle filtering half for sale packaged in are protected agains and contamination be	such a t mecha	way tha	at they	Appropriate	-	PASS
Part 7.5 Material	When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse.				Appropriate	-	PASS
Part 7.6 Cleaning and disinfecting	After cleaning and dis particle filtering half penetration requirenclass.	mask sh	nall sati	sfy the	Not applicable	-	Not applicable



# TECHNICAL EVALUATION REPORT (145-21-01-R01)

Part 7.7	No negative comments should be made by	Appropriate	1-	PASS
Practical performance	the test subject regarding any of the criteria evaluated.			17.03
Part 7.8 Finish of parts	Parts of the device likely to come into contact with the wearer shall have no sharp edge or burrs.		-	PASS

TESTS PAR	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3	1		
Part 7.9.1 Total inward leakage	At least 46 out of the 50 individual exercise result	<25	<11	<5	See the table below	FFP2	PASS
5000	At least 8 out of the 10 individual wearer arithmetic means	<22	<8	<2	See the table below	FFP2	PASS

	<b>Total Inwar</b>	d Leakage (%	6)			
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	5.9	6.8	5.0	6.3	6.4	6.1
Subject 2 (As recieved)	7.7	6.7	5.9	7.9	6.2	6.9
Subject 3 (As recieved)	7.4	5.0	5.5	6.2	6.1	6.0
Subject 4 (As recieved)	7.1	8.3	5.6	7.9	8.3	7.4
Subject 5 (As recieved)	7.0	7.7	7.5	8.0	8.3	7.7
Subject 6 (After temperature conditioning)	6.8	8.0	7.4	5.1	6.9	6.8
Subject 7 (After temperature conditioning)	7.1	7.4	5.6	6.2	8.4	6.9
Subject 8 (After temperature conditioning)	7.1	7.3	7.0	6.0	6.9	6.9
Subject 9 (After temperature conditioning)	7.2	8.3	6.8	6.9	7.1	7.3
Subject 10 (After temperature conditioning)	5.8	8.3	8.3	7.9	8.5	7.8

TESTS	PARAMETER	PERF	DRMAN	CE LEVELS	RESULTS	PERFORMANCE LEVELS		EVALUATION	
		FFP1	FFP2	FFP3					
Part 7.9.2 Penetration of filter	Sodium chloride, 95 L/min %, max	% 20	% 6	% 1	See the table below	FFP2		PASS	
material	Paraffin oil, 95 L/min %, max	% 20	% 6	% 1	See the table below			PASS	
Penetration	of filter material	Sodium Chloride (%)		Par	Paraffin Oil (%)				
As recieved						1.8		4.9	
As recieved					4.8			5.0	
As recieved					4.9			5.1	
After the sim	ulated wearing treatmen	t			4.7			5.4	
After the sim	ulated wearing treatmen	t			4.6			5.1	
After the sim	ulated wearing treatmen	4.8			5.2				
Mechanical s	trength and temperature	4.9			5.5				
Mechanical s	trength and temperature	5.2			5.7				
Mechanical s	trength and temperature	5.3		5.6					



# TECHNICAL EVALUATION REPORT (145-21-01-R01)

TESTS	PARAMETER			CE LEVELS	RESULTS	PE	RFORMANCE	EVALUATION	
	Vi Vi	FFP1	FFP2	FFP3		LE	/ELS		
Part 7.10	Materials shall not b	e know	n to be	likely to	Appropriate	-		PASS	
Compatibility	cause irritation or an	y other	adverse	effect to					
with skin	health								
Part 7.11	Mask shall not burn o	r not to	continu	e to burn	Flame not	-		PASS	
Flammibility	for more than 5 s				seen			Adoreses.	
Part 7.12	Shall not exceed an av	verage o	f%1		0,77	-		PASS	
Carbondioxide					0,72				
content of the					0,76				
inhalation air									
Part 7.13	It can be donned and	remove	d easily		Appropriate	-		PASS	
Head harness									
Part 7.14	The field of vision sha	all accep	table in	practical	Appropriate	-		PASS	
Field of vision	performance test.	M.			, ippropriete			1733	
Part 7.15	It shall withstand axia	lly a ten	sile forc	e of 10 N	Not applicable	-		Not	
Exhalation	apply for 10 s.						applicable		
valve(s)	If fitted, shall contin							1.00	
	after a continuous		on flow	of 300					
	L/min over a period o	of 30 s.							
TESTS	PARAMETER	PERFO	RMANC	E LEVELS	RESULTS	PERFORMANCE		EVALUATION	
		FFP1	FFP2	FFP3		LEV	ELS		
Part 7.16	Inhalation 30L/min	0,6	0,7	1,0	See the table	FFP	22	PASS	
Breathing		mbar	mbar	mbar	below				
Resistance	Inhalation 95L/min	2,1	2,4	3,0	See the table	FFP	2	PASS	
		mbar	mbar	mbar	below				
	Exhalation 160L/min	3,0	3,0	3,0	See the table	FFP	2	PASS	
		mbar	mbar	mbar	below				
<b>Breathing Resis</b>	tance (mbar)			Inhalat	ion 30L/min		Inhalation 9	5L/min	
As recieved				0,4			1,5		
As recieved				0.4			1,4		
As recieved				0.4			1,5		
After temperatu	ure conditioning			0.4			1,5		
After temperatu	ure conditioning			0.4					
	ure conditioning			0.3	0.4 1,4 0.3 1,5				
After the simulated wearing treatment					0.3 1,4				
	ted wearing treatment			0.4			1,5		
	ted wearing treatment			0.4			1,5		
After the flow co				-			-		
After the flow co				-	Transfer of the second		-		
After the flow co	onditioning			-		2	-		

Breathing Resistance 160L/min (mbar)	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As recieved	2,2	2,1	2,1	2,1	2,1
As recieved	2,1	2,1	2,2	2,2	2,2
As recieved	2,2	2,2	2,1	2,1	2,1



# TECHNICAL EVALUATION REPORT (145-21-01-R01)

After temperature conditioning	2,1	2,2	2,2	2,1	2,2
After temperature conditioning	2,1	2,1	2,1	2,2	2,1
After temperature conditioning	2,1	2,2	2,1	2,1	2,1
After the simulated wearing treatment	2,1	2,1	2,1	2,1	2,1
After the simulated wearing treatment	2,1	2,2	2,2	2,2	2,1
After the simulated wearing treatment	2,1	2,1	2,1	2,1	2,2
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-			
After the flow conditioning	-	-			-

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3	1	of the survival with the states of the survival states of the surviv	
Part 7.17	After clogging the	4	5	7	Not applicable	-	Not applicable
Clogging	inhalation	mbar	mbar	mbar	ACTION OF THE SALE SHOW OF THE SALES		
	resistances shall						
	not exceed.						
	(valved)						
	The exhalation resist	ance sh	all not	exceed	Not applicable	-	Not applicable
	3 mbar at 160 L/	min coi	ntinuous	s flow.			
	(valved)						
	After clogging the	3	4	5	Not applicable	-	Not applicable
	inhalation and	mbar	mbar	mbar			
	exhalation						
	resistances shall						
	not exceed.						
	(valveless)				21		
Part 7.18	All demountable par				Not applicable	-	Not applicable
Demountable	readily connected	and s	ecured	were	and with		
part	possible by hand.						

#### 9. DECISION

Analysis and examinations XBRGwhite, XBRGblack, XBRGsmall model coded personal protective equipment; Respiratory Protective Devices EN 149:2001 +A1:2009- Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

#### 10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- User Instruction

Reason for revision : Different color and size products have been added.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 10.05.2021