

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED
PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

MODÜL C2 - ÜRETİMİN DÂHİLİ KONTROLÜ VE ÜRÜNÜN RASTGELE
ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK

Belge No / Certificate No : 87092589
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 10.10.2024-10.10.2025
Belge Geçerlilik Tarihi / Document Validity Period : 1 yıl / 1 year
**Firma Unvanı ve Adresi /
Company Name and Address** : JEDX MEDCARE
Köysikuja 1, 01640 Vantaa, FINLAND

Marka / Model / Brand / Model : JedX 1852 W HL
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III

**Teknik Değerlendirme Rapor No/
Technical Evaluation Report No** : 87092589

Ürün Tipi / Product Type:

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

Ürünün Malzeme Bilgisi / Product Material Information: JedX 1852 W HL model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ JedX 1852 W HL model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Karar Verici / Approver

Şirket Müdürü / General Manager



MNA Laboratuvarları San. Tic.Ltd .Şti
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U-Form-002/Rev.07/03.07.2024

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**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (87092589)**

Notified Body Number: 2841

Report No : 87092589

Report Date : 10.10.2024

Application No : 87092589

1. COMPANY INFORMATION:

JEDX MEDCARE
Köysikuja 1, 01640 Vantaa, FINLAND

2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection filter 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



JedX 1852 W HL

5. PPE DIMENSIONS:

JedX 1852 W HL model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The mask is made of elastic strap, nonwoven fabric on the outer and inner layers and filter 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 EVALUATION AND MARKING:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.3	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS

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Visual inspection				
Banned Azo Dyes	< 30 mg/kg	< 5 mg/kg	-	PASS
Part 7.4 Packaging	Particle filtering half mask shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	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 disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable	-	Not applicable
Part 7.7 Practical performance	No negative comments should be made by the test subject regarding any of the criteria evaluated.	Appropriate	-	PASS
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.	Appropriate	-	PASS

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.1 Total inward leakage	At least 46 out of the 50 individual exercise result	≤25	≤11	≤5	-	-	-
	At least 8 out of the 10 individual wearer arithmetic means	≤22	≤8	≤2	-	-	-

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75
4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
10	135	142	125	83

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.2 Penetration of filter material	Sodium chloride, 95 L/min %, max	% 20	% 6	% 1	See the table below	FFP2	PASS
	Paraffin oil, 95 L/min %, max	% 20	% 6	% 1	See the table below	FFP2	PASS

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Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	0,9	2,1
As received	1,1	2,4
As received	1,3	1,8
After the simulated wearing treatment	1,5	2,7
After the simulated wearing treatment	1,4	1,9
After the simulated wearing treatment	1,7	2,2
Mechanical strength and temperature conditioning (120 mg)	2,5	4,1
Mechanical strength and temperature conditioning (120 mg)	2,2	5,9
Mechanical strength and temperature conditioning (120 mg)	2,4	4,7

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.10 Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health				Appropriate	-	PASS
Part 7.11 Flammability	Mask shall not burn or not to continue to burn for more than 5 s				-	-	-
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				-	-	-
Part 7.13 Head harness	It can be donned and removed easily				Appropriate	-	PASS
Part 7.14 Field of vision	The field of vision shall acceptable in practical performance test.				Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axially a tensile force of 10 N apply for 10 s. If fitted, shall continue to operate correctly after a continuous exhalation flow of 300 L/min over a period of 30 s.				Not applicable	-	Not applicable

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.16 Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP2	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,5	1,5
As received	0,5	1,5
As received	0,5	1,5
After temperature conditioning	0,4	1,4
After temperature conditioning	0,4	1,5
After temperature conditioning	0,4	1,4
After the simulated wearing treatment	0,4	1,4
After the simulated wearing treatment	0,5	1,4

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After the simulated wearing treatment	0,4	1,4
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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 received	2,5	2,5	2,5	2,5	2,5
As received	2,5	2,5	2,5	2,4	2,5
As received	2,5	2,5	2,4	2,5	2,4
After temperature conditioning	2,4	2,4	2,4	2,5	2,5
After temperature conditioning	2,4	2,4	2,4	2,4	2,5
After temperature conditioning	2,4	2,4	2,4	2,4	2,4
After the simulated wearing treatment	2,4	2,4	2,4	2,5	2,5
After the simulated wearing treatment	2,4	2,5	2,5	2,4	2,5
After the simulated wearing treatment	2,4	2,5	2,4	2,5	2,4
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP 1	FFP 2	FFP3			
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	Not applicable	-	Not applicable
	The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved)				Not applicable	-	Not applicable
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mbar	4 mbar	5 mbar	Not applicable	-	Not applicable
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured were possible by hand.				Not applicable	-	Not applicable
Part 9 Marking	The packaging information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.				Appropriate	-	PASS

9. ATTACHMENTS

- Test Reports (M-2024-01358, M-2024-01321)

CONTROLLER :

MNA LABORATORY
ANALYSIS REPORT

Report Nu. : M-2024-01321	Date : 2024-10-09 16:19:54	Page : 1 / 4	Rev:
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Purpose of Analysis	: Special request
Sample Send Org.	: SJT-Investment Group Oy / JedX Medcare
Address	: Köysikuja 1, 01640 Vntaa, Finland
Sample Acceptance Date	: 2024-10-02 17:58:19
Analysis Date	: 2024-10-02 00:33:53
Sample Quantity	: 120 Pieces
Sample Description	: JedX 1852 W HL
Other informations	:

Tests	Method	Expected performance level	Evaluation
Penetration Of Filter Material	EN 149+A1 Part 8.11, EN 13274-7		PASS (FFP2)
Breathing Resistance	EN 149+A1 Part 8.9		PASS (FFP2)

Penetration Of Filter Material

Device: Filter Test System

Measurement uncertainty: $\pm 0,080$

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Penetration Of Filter Material	Check the table.	FFP1 \leq 20 FFP2 \leq 6 FFP3 \leq 1	EN 149+A1 Part 8.11, EN 13274-7	PASS (FFP2)	-

	Sodium Chloride (%)	Paraffin Oil (%)
As received 1	0,9	2,1
As received 2	1,1	2,4
As received 3	1,3	1,8
After the simulated wearing treatment 1	1,5	2,7
After the simulated wearing treatment 2	1,4	1,9
After the simulated wearing treatment 3	1,7	2,2
Mechanical strength and temperature conditioning (120 mg) 1	2,5	4,1
Mechanical strength and temperature conditioning (120 mg) 2	2,2	5,9
Mechanical strength and temperature conditioning (120 mg) 3	2,4	4,7

MNA LABORATORY
ANALYSIS REPORT

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Breathing Resistance

Device: Breathing Resistance Tester

Measurement uncertainty: Inhalation 30L/min:±0,160, Inhalation 30 L/min:±0,026 Exhalation 160 L/min:0,046

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Breathing Resistance	Check the table.	See the limits table.	EN 149+A1 Part 8.9	PASS (FFP2)	-

Classification	30 L/min max basınç (mbar)	95 L/min max basınç (mbar)	160 L/min max basınç (mbar)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Inhalation	30 L/min	95 L/min
As received 1	0,5	1,5
As received 2	0,5	1,5
As received 3	0,5	1,5
After temperature conditioning 1	0,4	1,4
After temperature conditioning 2	0,4	1,5
After temperature conditioning 3	0,4	1,4
After the simulated wearing treatment 1	0,4	1,4
After the simulated wearing treatment 2	0,5	1,4
After the simulated wearing treatment 3	0,4	1,4
After the flow conditioning 1	-	-
After the flow conditioning 2	-	-
After the flow conditioning 3		

Exhalation 160L/min	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As received 1	2,5	2,5	2,5	2,5	2,5
As received 2	2,5	2,5	2,5	2,4	2,5
As received 3	2,5	2,5	2,4	2,5	2,4
After temperature conditioning 1	2,4	2,4	2,4	2,5	2,5

MNA LABORATORY ANALYSIS REPORT

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After temperature conditioning 2	2,4	2,4	2,4	2,4	2,5
After temperature conditioning 3	2,4	2,4	2,4	2,4	2,4
After the simulated wearing treatment 1	2,4	2,4	2,4	2,5	2,5
After the simulated wearing treatment 2	2,4	2,5	2,5	2,4	2,5
After the simulated wearing treatment 3	2,4	2,5	2,4	2,5	2,4
After the flow conditioning 1	-	-	-	-	-
After the flow conditioning 2	-	-	-	-	-
After the flow conditioning 3					

MNA LABORATORY ANALYSIS REPORT

Report Nu. : M-2024-01321	Date : 2024-10-09 16:19:54	Page : 4 / 4	Rev:
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4. Results are valid for the sample received.
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8. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pages, which are the supplementary part of this certificate.

The witness sample not recieved.

Nesligül Arkan

Sample Acceptance and Reporting Officer

2024-10-09 16:19:08



Erhan Üstünel

Laboratory Responsible

2024-10-09 16:18:57



VOLKAN AKIN

Laboratory Manager

2024-10-09 16:19:42



Report Nu. : M-2024-01358	Date : 2024-10-09 08:57:57	Page : 1 / 2	Rev:
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Purpose of Analysis	: Special request
Sample Send Org.	: SJT-Investment Group Oy / JedX Medcare
Address	: Köysikuja 1, 01640 Vntaa, Finland
Sample Acceptance Date	: 2024-10-07 08:19:50
Analysis Date	: 2024-10-07 08:34:18
Sample Quantity	: 4 Pieces
Sample Description	: Jedx black and green
Other informations	:

Tests	Method	Expected performance level	Evaluation
Banned Azo Dyes	EN ISO 14362-1 / EN ISO 17234-1		PASS

Banned Azo Dyes *

Device:GC-MS

Measurement uncertainty: Textile:±0,350 Leather:±0,390

Compounds/Cas No: biphenyl-4-ylamine, 4-aminobiphenyl xenylamine/92-67-1, benzidine/92-87-5, 4-chloro-o-toluidine/95-69-2, 2-naphthylamine/91-59-8, o-aminoazotoluene, 4-amino-2',3'-dimethylazobenzene, 4-o-tolylazo-o-toluidine/97-56-3, 5-nitro-o-toluidine/99-55-8, 4-chloroaniline/106-47-8, 4-methoxy-m-phenylenediamine/615-05-4, 4,4'-methylenedianiline, 4,4'-diaminodiphenylmethane/101-77-9, 3,3'-dichlorobenzidine, 3,3'-dichlorobiphenyl-4,4'-ylenediamine/91-94-1, 3,3'-dimethoxybenzidine, o-dianisidine/119-90-4, 3,3'-dimethylbenzidine, 4,4'-bi-o-toluidine/119-93-7, 4,4'-methylenedi-o-toluidine/838-88-0, 6-methoxy-m-toluidine p-cresidine/120-71-8, 4,4'-methylene-bis-(2-chloro-aniline), 2,2'-dichloro-4,4'-methylene-dianiline/101-14-4, 4,4'-oxydianiline/101-80-4, 4,4'-thiodianiline/139-65-1, o-toluidine, 2-aminotoluene/95-53-4, 4-methyl-m-phenylenediamine/95-80-7, 2,4,5-trimethylaniline/137-17-7, o-anisidine, 2-methoxyaniline/90-04-0, 4-amino azobenzene/60-09-3

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Banned Azo Dyes	Check the table.	≤30 mg/kg	EN ISO 14362-1 / EN ISO 17234-1	PASS	-

Part of Sample/ Numune kısımları	Results/ Sonuçlar(mg/kg)
Black Fabric+Black elastic earloop+Green elastic earloop	<5

MNA LABORATORY
ANALYSIS REPORTTest
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T

M-2024-01358

10-24

Report Nu. : M-2024-01358	Date : 2024-10-09 08:57:57	Page : 2 / 2	Rev:
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Operating as a test laboratory, MNA Laboratories is accredited by TÜRKAK according to AB-1183-T and TS_EN_ISO/IEC_17025:2017 standards has been done. A multilateral agreement with the European Accreditation Association (EA) on the recognition of the Turkish Accreditation Agency (TÜRKAK) test reports and It has signed a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).

*The analysis is within the scope of accreditation.

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8. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pages, which are the supplementary part of this certificate.

The witness sample was not received.

Nesligül Arkan

Sample Acceptance and Reporting Officer

2024-10-09 08:57:12

Erhan Üstünel

Laboratory Responsible

2024-10-09 08:56:16

VOLKAN AKIN

Laboratory Manager

2024-10-09 08:56:26