

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 : 54102127
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 22.10.2025-22.10.2026
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 1609 W HLV
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** : 54102127

Ürün 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: JedX 1609 W HLV model ürünleri kumaş, elastik
kayış, burun klipsi, soluk verme valfi ve filtre katmanını kullanılarak imal edilmiştir./ JedX 1609 W HLV model
products are manufactured using fabric, elastic strap, nose clip, exhalation valve filter layer.

Karar Verici / Approver

Şirket Müdürü / General Manager



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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) (54102127)**

Report No : 54102127

Report Date : 22.10.2025

Application No : 54102127

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 1609 W HLV

5. PPE DIMENSIONS:

JedX 1609 W HLV model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The mask is made of elastic strap, exhalation valve 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.

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**8. ANALYSIS EVALUATION AND MARKING:
EN 149:2001 +A1:2009**

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
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	See the table below	FFP3	PASS
	At least 8 out of the 10 individual wearer arithmetic means	≤22	≤8	≤2	See the table below	FFP3	PASS

Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	1,7	2,1	1,9	2,1	1,3	1,8
Subject 2 (As received)	2,0	1,5	0,5	2,0	1,1	1,4
Subject 3 (As received)	1,7	1,2	2,3	2,2	1,4	1,8
Subject 4 (As received)	1,7	1,4	1,1	2,4	1,5	1,6
Subject 5 (As received)	1,4	1,4	1,6	1,8	1,2	1,5
Subject 6 (After temperature conditioning)	2,4	1,8	1,6	2,1	1,2	1,8
Subject 7 (After temperature conditioning)	1,1	0,8	2,2	3,8	1,3	1,8
Subject 8 (After temperature conditioning)	1,9	2,2	2,0	1,9	1,5	1,9
Subject 9 (After temperature conditioning)	1,8	2,0	1,9	2,4	1,3	1,9
Subject 10 (After temperature conditioning)	1,1	1,8	1,6	1,8	1,9	1,6

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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	FFP3	PASS
	Paraffin oil, 95 L/min %, max	% 20	% 6	% 1	See the table below	FFP3	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	0,4	0,5
As received	0,3	0,7
As received	0,4	0,4
After the simulated wearing treatment	0,6	0,5
After the simulated wearing treatment	0,5	0,4
After the simulated wearing treatment	0,4	0,5
Mechanical strength and temperature conditioning	0,4	0,8
Mechanical strength and temperature conditioning	0,5	0,7
Mechanical strength and temperature conditioning	0,7	0,8

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				Flame not seen	-	PASS
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0,75 0,74 0,71	-	PASS
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.				Appropriate	-	PASS

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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	FFP3	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP3	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP3	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,8	2,6
As received	0,8	2,6
As received	0,7	2,5
After temperature conditioning	0,7	2,5
After temperature conditioning	0,7	2,5
After temperature conditioning	0,7	2,5
After the simulated wearing treatment	0,7	2,5
After the simulated wearing treatment	0,7	2,5
After the simulated wearing treatment	0,7	2,5
After the flow conditioning	0,7	2,5
After the flow conditioning	0,7	2,5
After the flow conditioning	0,7	2,5

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	2,6	2,6	2,6	2,6
As received	2,5	2,6	2,6	2,5	2,6
As received	2,6	2,5	2,6	2,6	2,6
After temperature conditioning	2,5	2,6	2,5	2,6	2,6
After temperature conditioning	2,5	2,5	2,5	2,6	2,5
After temperature conditioning	2,5	2,6	2,5	2,6	2,5
After the simulated wearing treatment	2,5	2,5	2,5	2,5	2,6
After the simulated wearing treatment	2,5	2,5	2,5	2,5	2,6
After the simulated wearing treatment	2,6	2,6	2,6	2,6	2,6
After the flow conditioning	2,6	2,6	2,6	2,6	2,6
After the flow conditioning	2,5	2,5	2,5	2,5	2,5
After the flow conditioning	2,5	2,5	2,6	2,5	2,5

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	3 mbar	4 mbar	5 mbar	Not applicable	-	Not applicable

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	exhalation resistances shall not exceed. (valveless)						
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured where 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-2022-0656, M-2024-01538)

CONTROLLER :

AB-1183-T

M-2024-01358

10-24

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

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*The analysis is within the scope of accreditation.

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2. Analysis results are valid for the sample sent and analyzed by the company/institution/individual to MNA Laboratories. represent the whole may not.
3. Unsigned and Unsealed reports are invalid.
4. Results are valid for the sample received.
5. The decision rule is the rule that determines how measurement uncertainty is taken into account when specifying compliance with an established specification. The customer may choose to apply and/or not apply the decision rule (except in cases where legislation/standards are mandatory). If the customer prefers to apply the decision rule; According to the TLM-052 Decision Rule Application instruction published on the www.mnalab.com website, the decision rule selected in agreement is applied and reported by stating the relevant analysis and decision rule method in the "Note" section. If the customer leaves the decision rule application to the laboratory's evaluation, MNA LABORATORIES applies the simple decision rule.
6. Limit Values are determined by taking from analysis methods.
7. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.
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

MNA LABORATORY ANALYSIS REPORT

Report Nu. : M-2022-0656	Date : 2022-09-19 16:36:04	Page : 1 / 5	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	: 2022-08-15 00:12:10
Analysis Date	: 2022-08-15 13:28:16
Sample Quantity	: 120 Pieces
Sample Description	: JedX 1609 W HLV
Other informations	:

Penetration Of Filter Material

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 (FFP3)	-

	Sodium Chloride (%)	Paraffin Oil (%)
As received 1	0,4	0,5
As received 2	0,3	0,7
As received 3	0,4	0,4
After the simulated wearing treatment 1	0,6	0,5
After the simulated wearing treatment 2	0,4	0,5
After the simulated wearing treatment 3	0,4	0,5
Mechanical strength and temperature conditioning (120 mg) 1	0,4	0,8
Mechanical strength and temperature conditioning (120 mg) 2	0,5	0,7
Mechanical strength and temperature conditioning (120 mg) 3	0,7	0,8

Carbon Dioxide Content Of The Inhalation Air

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Carbon Dioxide Content Of The Inhalation Air	Check the table.	Maximum %1	EN 149+A1 Part 8.7	PASS	-

	CO2 (%)
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MNA LABORATORY ANALYSIS REPORT

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Sample 1	0,75		
Sample 2	0,74		
Sample 3	0,71		

Total Inward Leakage

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Total Inward Leakage	Check the table.	See the limits table.	EN 149+A1 Part 8.5	PASS (FFP3)	-

	At least 46 out of the 50 individual exercise result shall be not greater than	At least 8 out of the 10 individual wearer arithmetic means shall be not greater than
FFP1	≤25	≤22
FFP2	≤11	≤8
FFP3	≤5	≤2

	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	1,7	2,1	1,9	2,1	1,3	1,8
Subject 2 (As received)	2,0	1,5	0,5	2,0	1,1	1,4
Subject 3 (As received)	1,7	1,2	2,3	2,2	1,4	1,8
Subject 4 (As received)	1,7	1,4	1,1	2,4	1,5	1,6
Subject 5 (As received)	1,4	1,4	1,6	1,8	1,2	1,5
Subject 6 (After temperature conditioning)	2,4	1,8	1,6	2,1	1,2	1,8
Subject 7 (After temperature conditioning)	1,1	0,8	2,2	3,8	1,3	1,8
Subject 8 (After temperature conditioning)	1,9	2,2	2,0	1,9	1,5	1,9
Subject 9 (After temperature conditioning)	1,8	2,0	1,9	2,4	1,3	1,9
Subject 10 (After temperature conditioning)	1,1	1,8	1,6	1,8	1,9	1,6

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Flammability

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Flammability	No flame seen.	Shall not burn for more than 5 sec after removal from the flame	EN 13274-4	PASS	-

Breathing Resistance

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 (FFP3)	-

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	0,8	2,6
As received 2	0,8	2,6
As received 3	0,7	2,5
After temperature conditioning 1	0,7	2,5
After temperature conditioning 2	0,7	2,5
After temperature conditioning 3	0,7	2,5
After the simulated wearing treatment 1	0,7	2,5
After the simulated wearing treatment 2	0,7	2,5
After the simulated wearing treatment 3	0,7	2,5
After the flow conditioning 1	0,7	2,5
After the flow conditioning 2	0,7	2,5
After the flow conditioning 3	0,7	2,5

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	2,6	2,6	2,6	2,6
As received 2	2,5	2,6	2,6	2,5	2,6

MNA LABORATORY ANALYSIS REPORT

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As received 3	2,6	2,5	2,6	2,6	2,6		
After temperature conditioning 1	2,5	2,6	2,5	2,6	2,6		
After temperature conditioning 2	2,5	2,5	2,5	2,6	2,5		
After temperature conditioning 3	2,5	2,6	2,5	2,6	2,5		
After the simulated wearing treatment 1	2,5	2,5	2,5	2,5	2,6		
After the simulated wearing treatment 2	2,5	2,5	2,5	2,5	2,6		
After the simulated wearing treatment 3	2,6	2,6	2,6	2,6	2,6		
After the flow conditioning 1	2,6	2,6	2,6	2,6	2,6		
After the flow conditioning 2	2,5	2,5	2,5	2,5	2,5		
After the flow conditioning 3	2,5	2,5	2,6	2,5	2,5		

MNA LABORATORY ANALYSIS REPORT

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*The analysis is within the scope of accreditation.

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2. Analysis results are valid for the sample sent and analyzed by the company/institution/individual to MNA Laboratories. represent the whole may not.
3. Unsigned and Unsealed reports are invalid.
4. This analysis report cannot be used in judicial-administrative proceedings and for advertising purposes.
5. Results are valid for the sample received.
6. A decision rule is a rule that determines how measurement uncertainty is to be taken into account when specifying compliance with a specified specification. TLM-052 Decision Rule According to the implementation instruction, the decision rule chosen in agreement with the customer will be applied if necessary.
7. Limit Values are determined by taking from analysis methods.
8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.
9. 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.
10. Water Repellency Determination Hydrostatic Pressure Determination T S ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (Strength Test Device E / N: 50) Analysis and resistance to liquid chemical permeation TS EN 659 -A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2 conditions (23 ± 2 ° C temperature and $50 \pm 4\%$ relative humidity) are applied for ambient conditions.

Selin Gergin

Sample Acceptance and Reporting Officer

2022-09-19 16:35:21

Erhan Üstünel

Laboratory Responsible

2022-09-19 16:09:33



VOLKAN AKIN
Laboratory Manager
2022-09-19 16:15:51

