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TÜRKAK
Product
TS EN ISO/IEC 17065
AB-0128-U

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

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

Belge No / *Certificate No* : 13092583
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 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* : 13092583
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, soluk verme valfi, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ *JedX 1609 W HLV model products are manufactured using fabric, elastic strap, exhalation valve, nose clip, filter layer.*

Karar Verici / Approver ***Şirket Müdürü / General Manager***

Digitally signed by FARUK SARIHAN
Date: 2024.10.10 16:53:11 +03'00'

Digitally signed by OKAN AKEL
Date: 2024.10.10 17:03:10 +03'00'

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Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (13092583)

Report No : 13092583

Report Date : 10.10.2024

Application No : 13092583

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.

8. **ANALYSIS EVALUATION AND MARKING:**

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP 2	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	-	-	-
	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	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	0,2	0,3
As received	0,2	0,4
As received	0,1	0,4
After the simulated wearing treatment	0,2	0,2
After the simulated wearing treatment	0,1	0,2
After the simulated wearing treatment	0,2	0,3
Mechanical strength and temperature conditioning (120 mg)	0,4	0,4
Mechanical strength and temperature conditioning (120 mg)	0,3	0,5
Mechanical strength and temperature conditioning (120 mg)	0,4	0,6

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.				Appropriate	-	PASS

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	0,4	1,5
As received	0,4	1,5
As received	0,4	1,5
After temperature conditioning	0,4	1,5
After temperature conditioning	0,3	1,5
After temperature conditioning	0,3	1,4
After the simulated wearing treatment	0,4	1,5
After the simulated wearing treatment	0,3	1,4
After the simulated wearing treatment	0,3	1,4
After the flow conditioning	0,4	1,5

After the flow conditioning	0,4	1,5
After the flow conditioning	0,3	1,5

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	2,4	2,4	2,4	2,4	2,4
As received	2,4	2,3	2,4	2,4	2,4
As received	2,4	2,4	2,4	2,4	2,3
After temperature conditioning	2,4	2,3	2,4	2,4	2,3
After temperature conditioning	2,4	2,4	2,4	2,3	2,4
After temperature conditioning	2,3	2,4	2,3	2,4	2,3
After the simulated wearing treatment	2,3	2,4	2,4	2,4	2,4
After the simulated wearing treatment	2,3	2,4	2,3	2,4	2,3
After the simulated wearing treatment	2,3	2,3	2,4	2,3	2,4
After the flow conditioning	2,3	2,4	2,3	2,4	2,3
After the flow conditioning	2,3	2,4	2,4	2,4	2,4
After the flow conditioning	2,3	2,4	2,3	2,4	2,3

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-2024-01329, M-2024-01358)

CONTROLLER : Digitally signed by FARUK SARIHAN
Date: 2024.10.10 16:52:47 +03'00'

MNA LABORATORY
ANALYSIS REPORT

Report Nu. : M-2024-01329	Date : 2024-10-09 16:04:53	Page : 1 / 4	Rev:

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 17:54:13
Analysis Date	: 2024-10-02 00:35:39
Sample Quantity	: 120 Pieces
Sample Description	: JedX 1609 W HLV
Other informations	:

Tests	Method	Expected performance level	Evaluation
Penetration Of Filter Material	**EN 149+A1 Part 8.11, EN 13274-7**		**PASS (FFP3)**
Breathing Resistance	**EN 149+A1 Part 8.9**		**PASS (FFP3)**

Penetration Of Filter Material

Device:Filter Test System

Measurement uncertainty:±0,080

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

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

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ANALYSIS REPORT

Report Nu. : M-2024-01329	Date : 2024-10-09 16:04:53	Page : 2 / 4	Rev:

Breathing Resistance

Device:Breathing Resistance Tester

Measurement uncertainty: Inhalation 30L/min:±0,160,Inhalation30 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 (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	**0,4**	**1,5**
As received 2	**0,4**	**1,5**
As received 3	**0,4**	**1,5**
After temperature conditioning 1	**0,4**	**1,5**
After temperature conditioning 2	**0,3**	**1,5**
After temperature conditioning 3	**0,3**	**1,4**
After the simulated wearing treatment 1	**0,4**	**1,5**
After the simulated wearing treatment 2	**0,3**	**1,4**
After the simulated wearing treatment 3	**0,3**	**1,4**
After the flow conditioning 1	**0,4**	**1,5**
After the flow conditioning 2	**0,4**	**1,5**
After the flow conditioning 3	**0,3**	**1,5**

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	**2,4**	**2,4**	**2,4**	**2,4**	**2,4**
As received 2	**2,4**	**2,3**	**2,4**	**2,4**	**2,4**
As received 3	**2,4**	**2,4**	**2,4**	**2,4**	**2,3**
After temperature conditioning 1	**2,4**	**2,3**	**2,4**	**2,4**	**2,3**

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ANALYSIS REPORT

Report Nu. : M-2024-01329	Date : 2024-10-09 16:04:53	Page : 3 / 4	Rev:

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

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ANALYSIS REPORT

Report Nu. : M-2024-01329	Date : 2024-10-09 16:04:53	Page : 4 / 4	Rev:

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The witness sample not recieved.

Nesligül Arkan

Sample Acceptance and Reporting Officer

2024-10-09 16:04:11

VOLKAN AKIN

Laboratory Manager

2024-10-09 16:04:23

Erhan Üstünel

Laboratory Responsible

2024-10-09 16:03:55

FRM:23/rev.06/27.10.2023

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MNA LABORATORY
ANALYSIS REPORT

Test
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 : 1 / 2	Rev:

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**

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MNA LABORATORY
ANALYSIS REPORT

AB-1183-T
M-2024-01358
10-24

Report Nu. : M-2024-01358	Date : 2024-10-09 08:57:57	Page : 2 / 2	Rev:

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).

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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 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

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