

## EVALUATION OF THE CONFORMITY

**2020EP1609UE**

### APPLICATION DATE

08/07/2020

### APPLICANT

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### IDENTIFICATION AND DESCRIPTION OF SAMPLES

#### REFERENCES

JUNIOR JN2024 GOWN

### TESTS CARRIED OUT

- OBSERVATIONS
- DESCRIPTION OF SAMPLE
- ESSENTIAL REQUIREMENTS
- EVALUATION FOR EU TYPE CERTIFICATION
- CONCLUSION OF THE CONFORMITY EVALUATION



## OBSERVATIONS

PPE TYPE GOWN referenced JUNIOR JN2024 GOWN presented for the “EU” Type certification to comply with the Regulation (EU) 2016/425, based on the standards EN 340:2003 and EN ISO 13688:2013 and EN 14126:2003/AC:2004

The manufacturer has presented the applicable technical documentation according to Annex III of the Regulation (UE) 2016/425.

The customer has presented the following samples:

- Two (2) complete garment from the PPE JUNIOR JN2024 GOWN

With compliance to the Regulation (EU) 2016/425.

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## DESCRIPTION OF SAMPLES

### JUNIOR JN2024 GOWN

Gown made in white non-woven fabric with an exterior white laminated.



The PPE is made in with the following materials according to technical documentation presented by the client:

- White non-woven fabric with an exterior white laminated, composition: 60% polyethylene and 40% polypropylene (3,6% Spunbond Hydrophobic Hotmelt) with an approximate weight of 55 g/m<sup>2</sup>.
- White knitted fabric (cuffs), composition: 100% polyester lycra lwith an approximate weight of 140 g/m<sup>2</sup>.
- Self-adhesive tape (back)
- Seams

The PPE is available in the following sizes:

SIZE	User chest girth (cm)	Wearer's height (cm)
S-M	130-136	115- 120
L-XL	136-142	120-125
XXLX-XXXL	142-148	125

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## ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

<b>Annex II Regulation (EU) 2016/425</b>	<b>Clauses of Standard EN 340:2003</b>
1.2.1 Absence of inherent risks and other nuisance factors	4.2
1.2.1.1. Suitable constituent materials	Annex B
1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user	4.4
1.3.1. Adaptation of PPE to user morphology	6
1.4. Manufacturer's instructions and information	8
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	6,7

<b>Annex II Regulation (EU) 2016/425</b>	<b>Clauses of Standard EN ISO 13688:2013</b>
1.2.1. Absence of inherent risks and other nuisance factors	5.3
1.2.1.1. Suitable constituent materials	4.2
1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user	4.4
1.4. Manufacturer's instructions and information	8
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	6,7

<b>Annex II Regulation (EU) 2016/425</b>	<b>Clauses of Standard EN 14126:2003/AC:2004</b>
1.1.2.2. Classes of protection appropriate to different levels of risk	4.1.4
1.3.1. Adaptation of PPE to user morphology	4.3
1.3.2 Lightness and strength	4.1.2, 4.2
1.4. Manufacturer's instructions and information	6
2.12 PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	5
3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents	4.3, 4.1.4

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## EVALUATION

The following points of the PPE TYPE GOWN referenced JUNIOR JN2024 GOWN, according to Regulation (EU) 2016/425 and the technical specifications applicable to it, according to the harmonized standard EN 340:2003 and EN ISO 13688:2013 and EN 14126:2003/AC:2004.

### 1.- TECHNICAL DOCUMENTATION AND MARKING

	RELATED DOCUMENT	ANNEX / CLAUSE	RESULTS
Technical documentation	Regulation (UE) 2016/425	Annex III	Achieved
Marking	EN 340:2003	7	Achieved
	EN ISO 13688:2013	7	
	EN 14126:2003/AC:2004	5	
Manufacturer information <sup>(1)</sup>	Regulation (UE) 2016/425	Annex II point 1.4	Achieved
	EN 340:2003	8	Achieved
	EN ISO 13688:2013	8	
	EN 14126:2003/AC:2004	6	

<sup>(1)</sup> It has been verified about the version in English presented by the client.

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## EVALUATION

### 2.- REQUIREMENTS

#### 2.1.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN ISO 13688:2013 and EN 340:2003

TEST	CLAUSE	REQUIREMENT	RESULTS	REPORT No.
Ergonomics	4	The garment fulfills ergonomics requirement	Achieved	2020EP1608
Innocuousness	4.2.a)	Chromium (VI) content in leather clothing shall not exceed 3 mg/kg	Not applicable	---
	4.2.b)	All metallic materials which could come into prolonged contact with the skin shall have a release of nickel of less than 0,5 µg/cm per week	Not applicable	---
	4.2.c)	Protective clothing material shall have a pH value greater than 3,5 and less than 9,5	External fabric Achieved	2020EP0204
			Cuffs fabric Achieved	2020EP1608
	4.2.d)	Forbidden azoic colorants shall not be detectable	External fabric Not detected	2020EP0204
			Cuffs fabric Not detected	2020EP1608
Design	4.3	The garment fulfills design requirement	Achieved	2020EP1608
Dimensional stability after 5 washing cycles 60°C	5.3	Changes of dimension due to cleaning shall not exceed 3% for woven materials and 5% for knitted material and nonwovens.	Not applicable	---
Sizing	6	Protective clothing shall be marked with its size based on body dimensions measured in centimetres.	Achieved	2020EP0204

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## EVALUATION

### 2.2.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 14126:2003/AC:2004

TEST	CLAUSE	REQUIREMENT	RESULTS	REPORT No.
Design	4.3	The garment fulfills design requirement	Achieved	2020EP1608
Resistance to abrasión	4.1.2	According to the point 4.4 of the Standard EN 14325: 2018 Class 1 10 < cycles < 40 Class 2 40 < cycles < 100 Class 3 100 < cycles < 400 Class 4 400 < cycles < 1000 Class 5 1000 < cycles < 2000 Class 6 > 2000 cycles	Class 3 Achieved	2020EP1608
Compression-folding flex cracking	4.1.2	According to the point 4.5 of the Standard EN 14325: 2018 Class 1 500 < cycles < 1250 Class 2 1250 < cycles < 3000 Class 3 3000 < cycles < 8000 Class 4 8000 < cycles < 20000 Class 5 20000 < cycles < 50000 Class 6 > 50000 cycles	Class 6 Achieved	2020EP0204

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## EVALUATION

### 2.2.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 14126:2003/AC:2004

TEST	CLAUSE	REQUIREMENT	RESULTS	REPORT No.
Compression-folding flex cracking at -30°C	4.1.2	According to the point 4.6 of the Standard EN 14325: 2018 Class 1 100 < cycles < 200 Class 2 200 < cycles < 500 Class 3 500 < cycles < 1000 Class 4 1000 < cycles < 2000 Class 5 2000 < cycles < 4000 Class 6 > 4000 cycles	Not applicable	---
Determination of tear resistance (trapezoidal)	4.1.2	According to the point 4.7 of the Standard EN 14325: 201/ Class 1 10 < N < 20 Class 2 20 < N < 40 Class 3 40 < N < 60 Class 4 60 < N < 100 Class 5 100 < N < 150 Class 6 > 150 N	Class 2 Achieved	2020EP0204

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## EVALUATION

### 2.2.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 14126:2003/AC:2004

TEST	CLAUSE	REQUIREMENT	RESULTS	REPORT No.
Tensile strength	4.1.2	According to the point 4.9 of the Standard EN 14325: 2018 Class 1 30 < N < 60 Class 2 60 < N < 100 Class 3 100 < N < 250 Class 4 250 < N < 500 Class 5 500 < N < 1000 Class 6 > 1000 N	Class 1 Achieved	2020EP0204
Puncture resistance	4.1.2	According to the point 4.10 of the Standard EN 14325: 2018 Class 1 5 < N < 10 Class 2 10 < N < 50 Class 3 50 < N < 100 Class 4 100 < N < 150 Class 5 150 < N < 250 Class 6 > 250 N	Class 1 Achieved	2020EP0204
Resistance to ignition	4.1.2	According to the point 4.14 of the Standard EN 14325: 2018 material shall not form droplets and it shall not continue to burn for more than 5 s after removal from the flame	Achieved	2020EP0204

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## EVALUATION

### 2.2.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 14126:2003/AC:2004

TEST	CLAUSE	REQUIREMENT	RESULTS	REPORT No.
Resistance to flame	4.1.2	<p>According to the point 4.15 of the Standard EN 14325: 2018 material shall not form droplets and it shall not continue to burn for more than 5 s after removal from the flame</p> <p>Class 1 Specimen stops for 5 s in the flame</p> <p>Class 2 Specimen stops for 1 s in the flame</p> <p>Class 3 Specimen passes through the flame without stopping</p>	Not tested	---
Resistance to permeation by chemicals	4.1.3	<p>According to the point 4.11 of the Standard EN 14325: 2018</p> <p>Class 1 10 &lt; min &lt; 30</p> <p>Class 2 30 &lt; min &lt; 60</p> <p>Class 3 60 &lt; min &lt; 120</p> <p>Class 4 120 &lt; min &lt; 240</p> <p>Class 5 240 &lt; min &lt; 480</p> <p>Class 6 &gt; 480 min</p>	Not tested	---

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## EVALUATION

### 2.2.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 14126:2003/AC:2004

TEST	CLAUSE	REQUIREMENT	RESULTS	REPORT No.
Repellency to liquids	4.1.3	According to the point 4.12 of the Standard EN 14325: 2018 Class 1 > 70% Class 2 > 80% Class 3 > 90%	Level 3 H2SO4 (30%) Level 3 NaOH (10%) Level 3 1-Butanol	2020EP0204
Resistance to penetration to liquids	4.1.3	According to the point 4.13 of the Standard EN 14325: 2018 Class 1 < 10% Class 2 < 5% Class 3 < 1%	Level 3 H2SO4 (30%) Level 3 NaOH (10%) Level 3 1-Butanol	2020EP0204
Resistance to penetration of contaminated liquids under hydrostatic pressure	4.1.4.1	Class 1 0 < kPa < 1,75 Class 2 1,75 < kPa < 3,5 Class 3 3,5 < kPa < 7 Class 4 7 < kPa < 14 Class 5 14 < kPa < 20 Class 6 > 20 kPa	Class 6 Achieved	2020EP0639
Resistance to the penetration of biological agents by mechanical contact with substances containing contaminated liquids	4.1.4.2	Class 1 t ≤ 15 min Class 2 15 < t < 30 Class 3 30 < t < 45 Class 4 45 < t < 60 Class 5 60 < t < 75 Class 6 t > 75 min	Class 1 Achieved	2020EP0639

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## EVALUATION

### 2.2.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 14126:2003/AC:2004

TEST	CLAUSE	REQUIREMENT	RESULTS	REPORT No.
Penetration resistance of contaminated liquid aerosols	4.1.4.3	Class 1 $1 < \log \leq 3$ Class 2 $3 < \log \leq 5$ Class 3 $\log > 5$	Not tested	---
Penetration resistance of contaminated solid particles	4.1.4.4	Class 1 $2 < \log ufc \leq 3$ Class 2 $1 < \log ufc \leq 2$ Class 3 $\leq 1$	Class 2 Achieved	2020EP0639
Seam strength	4.2	According to the point 5.5 of the Standard EN 14325: 2018 Class 1 $30 < N < 50$ Class 2 $50 < N < 75$ Class 3 $75 < N < 125$ Class 4 $125 < N < 300$ Class 5 $300 < N < 500$ Class 6 $> 500 N$	Class 3 Achieved	2020EP1608

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## EVALUATION

### 3.- SUMMARY OF VERIFICATION

**3.1.- APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 14126:2004/AC:2006**

**TEST REPORT:** 2020EP0204

**VERIFICATION REPORT:** 2020EP1608

TEST	RESULT TEST REPOR	RESULT VERIFIED	VERIFICATION
Determination of tear resistance	Class 2 Achieved	Class 2 Achieved	Meet
Resistance to Perforation	Class 1 Achieved	Class 1 Achieved	Meet
Penetration resistance of contaminated solid particles <sup>(1)</sup>	Class 2 Achieved	Class 3 Achieved	Meet

<sup>(1)</sup> The PPE verification value evaluated by AITEX in the 2020EP1608 test report is higher than the one in the 2020EP0204 test report, so we consider acceptable the verification

**For validation of verification have continued eligibility criteria according to the procedure PC-017**



## CONCLUSION OF THE CONFORMITY EVALUATION

AITEX, Notified Body N° 0161, concludes that:

The PPE JUNIOR JN2024 GOWN, complies with all essential Requirements as regards health and safety in compliance with the indications in (EU) 2016/425 in compliance with harmonised standards EN ISO 13688:2013 and EN 340:2003: "Protective Clothing – General Requirements", EN 14126:2003/AC:2004 for protection against biological agents (**Type PB 6-B**), being for resistance to penetration of contaminated liquids (Class 6), resistance to penetration of biological agents (Class 1) and resistance to penetration of contaminated solid particles (Class 2).

The CAT. III PPE shall only be used in conjunction with one of the conformity assessment procedures according to Module C2 or Module D described in Article 19 letter c) of the Regulation (EU) 2016/425.

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**Lucia Martinez**

**Head of PPE and Ballistics department**

#### LIABILITY CLAUSES

- 1.- AITEX is liable only for the results of the methods of analysis used, as expressed in the report and referring exclusively to the materials or samples indicated in the same which are in its possession, the professional and legal liability of the Centre being limited to these. Unless otherwise stated, the samples were freely chosen and sent by the applicant.
- 2.- AITEX shall not be liable in any case of misuse of the test materials nor for undue interpretation or use of this document
- 3.- The Offer and / or Order to which the applicant gives approval through signature and seal, constitutes the Legally Executable Agreement in which AITEX is responsible for safeguarding and guaranteeing the absolute confidentiality of the management of all the information obtained or created during the performance of the contracted activities.
- 4.- In the eventuality of discrepancies between reports, a check to settle the same will be carried out in the head offices of AITEX. Also, the applicants undertake to notify AITEX of any complaint received by them as a result of the report, exempting this Centre from all liability if such is not done, the periods of conservation of the samples being taken into account.
- 5.- AITEX is not responsible for the information provided by customers, which is reflected in the Report, and may affect the validity of the results.
- 6.- AITEX will provide at the request of the person concerned, the treatment of complaints procedure.
- 7.- AITEX is not responsible for an inadequate state of the sample received that could compromise the validity of the results, expressing such circumstance, in the test reports.
- 8.- AITEX may include in its reports, analyses, results, etc., any other evaluation which it considers necessary, even when it has not been specifically requested.
- 9.- When a Declaration of Conformity is requested, if not indicated otherwise, the decision rule will be applied according to ILAC-G8 & ISO 10576-1, in case of ambiguity, or indeterminacy
- 10.- The uncertainties of tests, which are made explicit in the Results Report, have been estimated for a  $k = 2$  (95% probability of coverage). If not informed, they are available to the client in AITEX.
- 11.- The original materials and rests of samples, not subject to test, will be retained in AITEX during the twelve months following the issuance of the report, so that any check or claim which, in his case, wanted to make the applicant, should be exercised within the period indicated.
- 12.- This report may only be sent or delivered by hand to the applicant or to a person duly authorised by the same.
- 13.- The results of the tests and the statement of compliance with the specification in this report refer only to the test sample as it has been analyzed / tested and not the sample / item which has taken the test sample.
- 14.- The client must attend at all times, to the dates of the realization of the tests.
- 15.- According to Resolution EA (33) 31, the test reports must include the unique identification of the sample, and any brand or label of the manufacturer may be added. It is not allowed to re-issue test reports of untested sample names (references), they can only be re-issued for error correction or inclusion of omitted data that were already available at the time of the test. The laboratory can not assume responsibility for declaring that the product with the new trade name / trademark is strictly identical to the one originally tested; This responsibility belongs to the client.