

CONFORMITY ASSESSMENT

2024US0485UE

APPLICATION DATE

Date Format: dd/MM/yyyy 24/10/2024

APPLICANT

HexArmor
640 Leffingwell Ave NE
US-49505 Grand Rapids
United States

Att. Michael Hasler

IDENTIFICATION AND DESCRIPTION OF SAMPLES

Reference by AITEX	Reference by customer	AITEX sample description
2024US0485-S01	Helix 2065	Gloves

TASKS CARRIED OUT

- OBSERVATIONS
- SAMPLE/S DESCRIPTION
- ESSENTIAL HEALTH AND SAFETY REQUIREMENTS
- CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION



OBSERVATIONS

PPE TYPE GLOVE referenced Helix 2065, presented for the “EU” Type certification to comply with the Regulation (EU) 2016/425, based on the standards EN ISO 21420:2020 and EN 388:2016+A1:2018.

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

The customer has presented the following samples:

- Twenty (20) complete garment from the PPE Helix 2065

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



SAMPLE/S DESCRIPTION

A five-fingered glove made in marbled black and white knitted fabric. It has a blue coating at the hand and a black coating covering entire palm. On the back, this black coating covers the upper part of the fingers.



The weight of a pair of size L gloves is approximately 104 g.

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

- Marbled black and white knitted fabric: 50% HPPE, 20% Glass Fibre, 22% Nylon® and 8% Spandex®
- Blue nitrile coating
- Black nitrile coating
- Thermo-sealed logo
- Green piping

The PPE is available in the following sizes:

SIZES	User's hand length (mm)	Circumference of hand (mm)
XX-Small (5)	209	147
X-Small (6)	221	157
Small (7)	228	167
Medium (8)	232	177
Large (9)	240	187
X-Large (10)	244	197
XX-Large (11)	259	207
XXX-Large (12)	265	217



ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

Annex II Regulation (EU) 2016/425	Clauses of Standard EN ISO 21420:2020
1.2.1.1. Suitable constituent materials	4.2
1.2.1.3. Maximum permissible user impediment	5.2
1.3.1. Adaptation of PPE to user morphology	5.1
1.4. Manufacturer's instructions and information	7.3
2.2. PPE enclosing the parts of the body to be protected	5.3
2.4. PPE subject to ageing	4.3, 7.2
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	7.2; Annex C

Annex II Regulation (EU) 2016/425	Clauses of Standard EN 388:2016+A1:2018
1.4. Manufacturer's instructions and information	7; 8
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	7
3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle	4.2.1
3.3. Protection against mechanical injuries	4.1



CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION

The following points of the PPE TYPE GLOVE referenced Helix 2065 have been evaluated according to Regulation (EU) 2016/425 and the technical specifications applicable to it, according to the standard EN ISO 21420:2020 and EN 388:2016+A1:2018.

1.- DOCUMENTATION AND MARKING

	RELATED DOCUMENT	ANNEX / CLAUSE	RESULTS
Technical documentation.	Regulation (UE) 2016/425	Annex III	Achieved
Marking	EN ISO 21420:2020	7.2	Achieved
	EN 388:2016+A1:2018	7	
Manufacturer information ⁽¹⁾	Regulation (UE) 2016/425	Annex II point 1.4	Achieved
	EN ISO 21420:2020	7.3	Achieved
	EN 388:2016+A1:2018	8	

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



CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION

2.- REQUIREMENTS

2.1.-APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN ISO 21420:2020

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Design	4.1	The glove fulfills design requirement	Achieved	2024US0359
Ergonomics	4.1	The glove fulfills ergonomics requirement	Not applicable	---
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 glove material shall have a pH value greater than 3,5 and less than 9,5	MAIN FABRIC BLUE Achieved	2024US0359
			PALM Achieved	2024US0359
			CUFF Achieved	2024US0359
			YELLOW PIPING Achieved	2024US0359
			PURPLE PIPING Achieved	2024US0359
			WHITE PIPING Achieved	2024US0359
			RED PIPING Achieved	2024US0359
			GREEN PIPING Achieved	2024US0359
			BROWN PIPING Achieved	2024US0359
			BLACK PIPING Achieved	2024US0359
			BLUE PIPING Achieved	2024US0359
			WHITE INNER FABRIC Achieved	2024US0359



CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION

2.- REQUIREMENTS

2.1.-APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN ISO 21420:2020

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Innocuousness	4.2 d)	Forbidden azo colorants shall not be detectable	MAIN FABRIC BLUE Not detected	2024US0525
			PALM Not detected	2024US0357
			CUFF Not detected	2024US0359
			YELLOW PIPING Not detected	2024US0359
			PURPLE PIPING Not detected	2024US0359
			WHITE PIPING Not detected	2024US0359
			RED PIPING Not detected	2024US0359
			GREEN PIPING Not detected	2024US0359
			BROWN PIPING Not detected	2024US0359
			BLACK PIPING Not detected	2024US0359
			BLUE PIPING Not detected	2024US0359
			WHITE INNER FABRIC Not detected	2024US0359
	4.2 e)	DMFa in gloves containing polyurethane must have a value less than 1000 mg / kg	Not applicable	---
	4.2 f)	PAHs shall not exceed 1 mg/kg for the rubber or plastic materials intended to come in direct contact with the skin	Not applicable	---

**CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION****2.1.-APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN ISO 21420:2020**

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Electrostatic properties	4.4.1	If required, electrostatic properties must be tested in accordance with the test method described in standards or EN 1149-1 or EN 1149-3	Not applicable	---
Sizing	5.1	Protective glove shall be marked with its size based on body dimensions measured in centimetres	Achieved	2024US0357
Dexterity	5.2	Level 1 11 mm Level 2 9,5 mm Level 3 8 mm Level 4 6,5 mm Level 5 5 mm	Level 5 Achieved	2024US0385

**CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION****2.1.-APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN ISO 21420:2020**

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Water vapour transmission ⁽¹⁾	5.3.1	If required, gloves should have a water vapour transmission ≥ 5 mg/cm ² ·h for leather gloves and ≤ 30 m ² Pa/W for textile gloves	Not tested	---
Water vapour absorption ⁽¹⁾	5.3.2	When the characteristics of the glove prevent the transmission of water vapor, the glove should reduce perspiration as much as possible and, if required, have a water vapor absorption ≥ 8 mg/cm ² ·8h for leather gloves	Not applicable	---

⁽¹⁾ Due to their low water vapor transmission and water vapour absorption, this glove has a restriction of use for a limited time



CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION

2.2.-APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 388:2016+A1:2018

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Abrasion resistance	6.1	Level 1: $100 \leq n < 500$ Level 2: $500 \leq n < 2000$ Level 3: $2000 \leq n < 8000$ Level 4: $n > 8000$	Level 4 Achieved	2024US0359
Blade cut resistance	6.2	Level 1: $1,2 \leq l < 2,5$ Level 2: $2,5 \leq l < 5$ Level 3: $5 \leq l < 10$ Level 4: $10 \leq l < 20$ Level 5: $l > 20$	Level X ⁽¹⁾	2024US0359
Tear resistance	6.4	Level 1: $10 \leq N < 25$ Level 2: $25 \leq N < 50$ Level 3: $50 \leq N < 75$ Level 4: $N > 75$	Level 4 Achieved	2024US0359
Puncture resistance	6.5	Level 1: $20 \leq N < 60$ Level 2: $60 \leq N < 100$ Level 3: $100 \leq N < 150$ Level 4: $N > 150$	Level 2 Achieved	2024US0359

⁽¹⁾ Cutting level cannot be declared due to dulling of the blade.

**CONFORMITY ASSESSMENT FOR EU TYPE-EXAMINATION****2.2.-APPLICABLE REQUIREMENTS ACCORDING TO THE STANDARD EN 388:2016+A1:2018**

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Resistance to cutting by sharp objects	6.3	Level A $2 \leq N < 5$ Level B $5 \leq N < 10$ Level C $10 \leq N < 15$ Level D $15 \leq N < 22$ Level E $22 \leq N < 30$ Level F $N > 30$	Level D Achieved	2024US0359
Impact protection (optional)	6.6	When required, the glove against mechanical risks must be designed and constructed to provide specific impact attenuation by performing tests in accordance with point 6.6 of the standard, obtaining at least a level 1 in accordance with EN 13594: 2015, Table 7.	Not tested	---



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21697627W

TECHNICAL CONDITIONS

- 1.- These conditions apply on the basis of AITEX standard terms and conditions of business and those contained in the current certification agreement.
- 2.- The certificate shall be issued in accordance with Annex V (Module B) of the PPE Regulation (EU) 2016/425.
- 3.- Where the product is classified as category III, CE marking of the production is dependent on current compliance with module C2 or module D of Regulation (EU) 2016/425 (unless specifically produced to suit an individual user).
- 4.- Full details of the scope of certification and the certified product(s) are contained in the manufacturer's technical documentation.
- 5.- Certification is limited to production carried out at the locations indicated in the manufacturer's technical documentation.
- 6.- The current manufactured product shall be consistent with the certified product(s) and listed in the certificate, and an EU declaration of conformity of the product in accordance with Regulation (EU) 2016/425 shall be available.
- 7.- The manufacturer shall inform AITEX of any changes to the certified product or to the technical documentation.
- 8.- When the results obtained during type testing are within the estimated uncertainty when compared to the specification, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market complies with the declared requirements, classifications or performance levels.
- 9.- This certificate shall be kept together with the relevant technical documentation in a safe place by the customer named on this certificate. The presentation of this certificate and other documentation may be required by a representative of the EC Member State.
- 10.- This certificate refers only to the state of the testable elements at the time of the certification procedure and is subject to the expiry date indicated.
- 11.- AITEX reserves the right to withdraw this certificate if it is found that the manufacturing conditions, design, materials or packaging have been modified and therefore no longer meet the requirements of Regulation (EU) 2016/425.
- 12.- AITEX is responsible for safeguarding and guaranteeing through this Legal Agreement, the absolute confidentiality of the management of all information obtained or created during the performance of the contracted activities. With the exception of information that the customer makes available to the public, or where there is an agreement between AITEX and the customer (e.g. for the purpose of responding to complaints), all information is considered private information and is therefore considered confidential. AITEX shall inform the customer in advance of the information it intends to make available to the public. Where AITEX is required by law or authorised by contractual provisions to disclose confidential information, the customer or person concerned shall be notified of the information provided unless prohibited by law. The above treatment shall also apply to information relating to the customer which is obtained from sources other than the customer (e.g. from a complaint or from regulatory authorities) and which is confidential because it is not available to the public.
- 13.- AITEX shall provide, upon request, the procedure for handling complaints. If you wish to make a complaint, please address it to: calidad@aitex.es.
- 14.- For all questions or proceedings that may arise from this request, the Company expressly submits to the AITEX Bylaws and Regulations.
- 15.- The supply of solutions cannot be included as a service.
- 16.- In the event that the PPE conformity assessment is completed by the Notified Organism (N.O.) and the modification of any documentation related to the certification file is pending on the part of the client, the N.O. will issue the conformity assessment report and proceed to invoice the entire certification process (prior notice). The PPE certificate will be issued when AITEX receives evidence of the pending modifications.