

TECHNICAL REPORT FOR EU TYPE-EXAM CERTIFICATION of Personal Protective Equipment (PPE)

EU TYPE EXAMINATION Nº:

UE-000052/00

APPLICATION DATE:

11/05/2021

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APPLICANT:

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PPE TYPE:

GLOVE

REFERENCE (PPE):

20210420

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ANNEX. - EU Type-Examination Certificate

1. PPE IDENTIFICATION

1.1 Description and photography

Gloves that completely covers the hand adapting to its form with individual cover for each of the fingers.



1.2 Description of the components

PPE components according to the information supplied by the manufacturer, are:

Powdered Natural Rubber Latex Gloves (Light Weight)

- Single-use item (disposable)
- Manufactured with powder free latex; color Off White to Yellow
- Anatomically adjustable
- Elastic, comfortable and resistant material.
- Ambidextrous

1.3 Sizes

According to the information supplied by the manufacturer, this PPE is commercialized in the following sizes:

Size	Length of the user's hand (mm)	Perimeter of the user's hand (mm)
6-7 S	160 – 171	152 – 178
7-8 M	171 – 182	178 – 203
8-9 L	182 – 192	203 – 229

1.4 Samples given for certification

On 24/04/2021, 200 gloves arrived to the laboratory and on 05/05/2021 we receive 300 more gloves. A total of 500 gloves with the reference 20210420

2. CERTIFICATION SCOPE

- EN 420:2003+A1:2009 Protective gloves - General requirements and test methods.
- EN ISO 21420:2020 Protective gloves - General requirements and test methods.

This European Standard is a reference standard referred to in the specific European standards relating to or applicable to protective gloves. This standard should not be used alone, but should only be used in combination with the appropriate specific standard.

The norm EN ISO 374:2016 establish the requirements for gloves focus on the user's protection against chemicals and micro-organisms.

Chemicals can cause seriously harm for both the personal health and the environment.

- EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. –Part 5: Terminology and performance requirements for micro-organisms risks.

Protection of the user's hands against the following risk:

- Risk of contact with microorganisms.

The gloves offer protection against micro-organisms: bacteria, fungus and viruses.

3. DOCUMENTATION SUBMITTED

- Technical documentation, including the next points:
- Complete description of the PPE and of its intended use
- Assessment of the risks against which the PPE is intended to protect
- List of the essential health and safety requirements that are applicable
- Design and manufacturing drawings and schemes of the PPE and of its components and explanations
- Reference of the harmonized standards and/ or other technical specifications
- Reports on the tests carried out to verify the conformity of the PPE
- A description of the means used by the manufacturer during the production (Modulo C)
 - Manufacturer's instructions
 - Marking
 - Declaration of conformity

4. RELATIONSHIP BETWEEN THIS EUROPEAN STANDARD AND ANNEX II OF REGULATION (EU) 2016/425 OF PPE

- **EN 420:2003+A1:2009** Protective gloves - General requirements and test methods

Essential Health and Safety Requirements, according to Annex II of Regulation (EU) 2016/425	Clause(s) / sub-clause(s) of the standard EN 420:2003+A1:2009	Result
1.2.1.1 Suitable constituent materials	4.3	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
1.2.1.3 Maximum permissible user impediment	5.2	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
1.3.1 Adaptation of PPE to user morphology	5.1	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
1.4 Manufacturer's instructions and information	7.3	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
2.2 PPE enclosing the parts of the body to be protected	5.3	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
2.4 PPE subject to ageing	4.4 and 7.2.3	Meet <input type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input checked="" type="checkbox"/>
2.12 PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	7.2 and Annex B	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>

- **EN ISO 21420:2020** Protective gloves - General requirements and test methods

Essential Health and Safety Requirements, according to Annex II of Regulation (EU) 2016/425	Clause(s) / sub-clause(s) of the standard EN ISO 21420:2020	Result
1.2.1.1 Suitable constituent materials	4.2	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
1.2.1.3 Maximum permissible user impediment	5.2	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
1.4 Manufacturer's instructions and information	7.3	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
2.4 PPE subject to ageing	4.3; 7.2.1.1 f) and 7.2.2 g)	Meet <input type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input checked="" type="checkbox"/>
2.5 PPE which may be caught up during use	7.3.7	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
2.6 PPE for use in potentially explosive atmospheres	4.4	Meet <input type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input checked="" type="checkbox"/>

2.12 PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	7.2.1.1 d); 7.2.2 e) and 7.3.5	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>

- **EN ISO 374-5:2016** Protective gloves against dangerous chemicals and micro-organisms. Part 5: Terminology and performance requirements for micro-organisms risks.

Essential Health and Safety Requirements, according to Annex II of Regulation (EU) 2016/425	Clause(s) / sub-clause(s) of the standard EN ISO 374-5:2016	Result
1.4 Manufacturer's instructions and information	7	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
2.12 PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	6	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>
3.10 Protection against dangerous substances and infective agents 3.10.2 Protection against cutaneous and ocular contact	5.2, 5.3, 5.4	Meet <input checked="" type="checkbox"/>
		Not meet <input type="checkbox"/>
		Not applicable <input type="checkbox"/>

5. DESIGN EVALUATION

- EN 420:2003+A1:2009 Protective gloves - General requirements and test methods

Requirements	Evaluation
The protective glove is designed and manufactured so that in the foreseeable conditions of use for which it is intended, the user can perform the hazard related activity normally whilst enjoying appropriate protection at the highest possible level.	Meet <input checked="" type="checkbox"/>
	Not meet <input type="checkbox"/>
	Not applicable <input type="checkbox"/>
The glove is designed to minimize the time needed for putting on and taking off.	Meet <input checked="" type="checkbox"/>
	Not meet <input type="checkbox"/>
	Not applicable <input type="checkbox"/>
In a glove with seams, both the material and strength of the seams is such that the overall performance of the glove is not significantly decreased.	Meet <input type="checkbox"/>
	Not meet <input type="checkbox"/>
	Not applicable <input checked="" type="checkbox"/>

6. SIZING EVALUATION

- EN 420:2003+A1:2009 Protective gloves - General requirements and test methods

Glove size: M 7/8

SAMPLE	MEASUREMENTS (glove)	DIMENSIONS (mm)
1	Glove circumference (mm)	190
	Total length (mm)	242
2	Glove circumference (mm)	190
	Total length (mm)	244
3	Glove circumference (mm)	192
	Total length (mm)	244

Chart of sizes, according to Technical Documentation provided:

Size	Length of the user's hand (mm)	Perimeter of the user's hand (mm)
6-7 S	160 – 171	152 – 178
7-8 M	171 – 182	178 – 203
8-9 L	182 – 192	203 – 229

After checking the dimensions of the protective glove size **M 7/8** and the measurements, by size to be marketed, provided by the customer in its Technical Documentation, it is declared:

Acceptable

Not acceptable

7. DEXTERITY

- EN 420:2003+A1:2009 and EN ISO 21420:2020 Protective gloves - General requirements and test methods

Test result:

GLOVE SIZE	Smallest diameter of pin fulfilling test conditions (mm)
M 7/8	5,0
M 7/8	5,0
M 7/8	5,0

Requirement:

Level of performance	Diameter of pin (mm)
1	11,0
2	9,5
3	8,0
4	6,5
5	5,0

After checking the evaluation of the dexterity, according to the method described in point 6.2 of the standard, it declares:

Level of performance 0

Level of performance 1

Level of performance 2

Level of performance 3

Level of performance 4

Level of performance 5

8. SUMMARY OF RESULTS

LEGEND RESULTS	
M	Meet
NM	Not meet
NA	Not applicable
NT	Not tested

8.1 EN 420:2003+A1:2009 Protective gloves. General requirements and test methods

TEST	BE APPLICATED	STANDARD	REQUERIMENTS	*UoM.	REPORT Nº	RESULT
Glove design and construction – General point 4.1	Glove	EN 420:2003+A1:2009, point 4.1	EN 420:2003+A1:2009, point 4.1	NA	Point 5 of this report	M
Resistance of glove materials to water penetration point 4.2	Textile/ external assembly	EN ISO 20811 (textils) EN 344-1:1992, point 5.12 (Leather)	EN 420:2003+A1:2009, point 4.2 EN ISO 20811 (textiles) Table 1 (Leather)	NT	NT	NT
Determination of pH value point 4.3.2	All materials	Others EN ISO 3071 Leather EN ISO 4045	EN 420:2003+A1:2009, point 4.3.2 The glove material shall have a pH value between 3,5 and 9,5.	± 0,3	AR-21-YL-006424-01	M
Cr (VI) Level point 4.3.3	Each layer of material (leather)	EN ISO 17075:2007	EN 420:2003+A1:2009, point 4.3.3 Must stay < 3mg/kg	NA	NA	NA
Determination of the free protein content, point 4.3.4	Rubber	EN 455-3	EN 420:2003+A1:2009, point 4.3.4 EN 455-3 If the glove contains any substances known to cause allergic reactions, it shall be stated in the product information	NA	AR-21-YL-006431-01	M
Cleaning point 4.4	Glove	-	EN 420:2003+A1:2009, point 4.4	NA	NA	NA
Electrostatic properties point 4.5	Textile/ external assembly	EN 1149-1 o EN 1149-2 o EN 1149-3	EN 420:2003+A1:2009, point 4.5	NT	NT	NT
Sizing point 5.1	Glove	EN 420:2003+A1:2009, point 5.1	EN 420:2003+A1:2009, point 5.1 The glove sizes are standardized according to minimum length.	± 0,1	Point 6 of this report	M
Dexterity point 5.2	Glove	EN 420:2003+A1:2003, point 5.2	EN 420:2003+A1:2009 Table 4	NA	Point 7 of this report	Level 5
Determination of the transmission of water vapor point 5.3.1	Textile/ external assembly	EN 420:2003+A1:2009, point 6.3 (IUP 15)	EN 420:2003+A1:2009, point 5.3.1 5mg/(cm ² ·h)	NT	NT	NT
Determination of water vapour absorption point 5.3.2	Textile/ external assembly	EN 420:2003+A1:2009, point 6.3 (IUP 15)	EN 420:2003+A1:2009, point 5.3.2 8mg/cm ² ·8h)	NT	NT	NT

Marking and information – General point 7.1	EN 420:2003+A1:2009, point 7.1	NA	NA	M
Marking point 7.2	EN 420:2003+A1:2009, point 7.2	NA	NA	M
Information supplied by the manufacturer point 7.3	EN 420:2003+A1:2009, point 7.3	NA	NA	M

8.2 EN ISO 21420:2020 Protective gloves. General requirements and test methods.

TEST	BE APLICATED	STANDARD	REQUERIMENTS	*UoM.	REPORT Nº	RESULT
Determination of content in Chromium (VI) point 4.2	Each layer of material (Leather)	ISO 17075-1 o ISO 17075-2	EN ISO 21420:2020, point 4.2 ≤ 3mg/kg	NA	NA	NA
Release of nickel point 4.2	All metallic materials in contact	EN 1811+A1:2015	EN ISO 21420:2020, point 4.2 < 0,5µg/cm ² per week	NA	NA	NA
Determination of pH point 4.2	All glove materials	Leather ISO 4045 Others ISO 3071	EN ISO 21420:2020, point 4.2 > 3,5 and < 9,5	± 0,3	AR-21-YL-006424-01	M
Determination of azo colorants which release carcinogenic amines point 4.2	All materials	Textile EN 14362-1 Leather ISO 17234-1	EN ISO 21420:2020, point 4.2 Shall be not detectable	NA	AR-21-YL-006424-01	M
Dimethylformamide (DMFa) point 4.2	PU	EN 16778	EN ISO 21420:2020, point 4.2 ≤ 1000 mg/kg (0,1% weight/weight)	NA	NA	NA
Determination of Polycyclic aromatic hydrocarbons (PAHs) point 4.2	Rubber or plastic materials in contact with the skin	ISO / TS 16190	EN ISO 21420:2020, point 4.2 and table 1 ≤ 1 mg/kg (0,0001% by mass+ of this component)	8 - 15 %	AR-21-YL-005046-01	M
Cleaning point 4.3	Glove	-	EN ISO 21420:2020, point 4.3 and 7.3.14	NA	NA	NA
Electrostatic properties point 4.4.1	Exterior fabric / assembly	EN 16350	EN ISO 21420:2020, point 4.4.1 Additional electrostatic properties determined by the test standards EN 1149-1 or EN 1149-3	NT	NT	NT
Dexterity point 5.2	Glove	ISO 21420:2020, point 6.2	EN ISO 21420:2020, point 5.2 and table 2	NA	Point 7 of this report	Level 5
Marking point 7.2.1.1 (d and f) and 7.2.2 (e and g)	EN ISO 21420:2020, point 7.2.1.1 (d and f) and 7.2.2 (e and g)			NA	NA	M
Information supplied by the manufacturer point 7.3.5 and 7.3.7	EN ISO 21420:2020, point 7.3.5 and 7.3.7			NA	NA	M

8.3 EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms.

Part 5: Terminology and performance requirements for micro-organisms risks.

TEST	BE APLICATED	STANDARD	REQUERIMENTS	*UoM.	REPORT Nº	RESULT												
General requirements point 5.1	Glove	-	Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.	NA	NA	M												
Penetration Air leak, point 5.2	Glove	EN ISO 374-2:2014, point 7.2 and 7.3	EN ISO 374-5:2016, point 5.2 Shall not leak	NA	AR-21-YL-006424-01	M												
Penetration Water leak, point 5.2				NA	AR-21-YL-006424-01	M												
Protection against viruses. Bacteriophage ⁽¹⁾ point 5.3	Glove outer fabric / assembly. Seams (if applicable)	ISO 16604 (Procedure B)	EN ISO 374-5:2016, point 5.3 Shall exhibit no detectable transfer of the bacteriophage in the assay title	NA	AR-21-YL-006429-01	M												
Requirements for different protection types of gloves, point 5.4	-	-	EN ISO 374-5:2016, point 5.4 and Table 1 <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>5.1</th> <th>5.2</th> <th>5.3</th> </tr> </thead> <tbody> <tr> <td>Gloves protecting against bacteria and fungi</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> </tr> <tr> <td>Glove protecting against virus, bacteria and fungi</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> </tr> </tbody> </table> X= required 5.1 Shall comply with the requirements given in EN 420:2009, point 4, point 5, and point 7		5.1	5.2	5.3	Gloves protecting against bacteria and fungi	X	X		Glove protecting against virus, bacteria and fungi	X	X	X	NA	NA	M
	5.1	5.2	5.3															
Gloves protecting against bacteria and fungi	X	X																
Glove protecting against virus, bacteria and fungi	X	X	X															
Marking point 6	EN ISO 21420, point 7 + EN ISO 374-5:2016, point 6			NA	NA	M												
Information supplied by the manufacturer point 7	EN ISO 21420, point 7.3 + EN ISO 374-5:2016, point 5.4 y 7			NA	NA	M												

(1) Test for protection marking including against viruses.

9. CONCLUSION

Based on the results obtained in the exams, evaluations and revisions the following can be deduced:

The PPE type **GLOVE** reference **20210420**, classified as Category **III** Individual Protective Equipment and whose characteristics are stated in point 1 of this report, **COMPLIES** with the essential requirements established by Regulation (EU) 2016/425 of 9 March 2016 through the application of the standards and risks as stated in point 2 of this report.

Elche, 27nd of July 2021

Signature of the conformity evaluator: