



# EU-TYPE EXAMINATION CERTIFICATE



The following model of Personal Protective Equipment has been subjected to an EU-type examination in accordance with the module B of the PPE regulation (2016/425) and has been shown to satisfy to essential health and safety requirements.

**Certificate N°** 0075/1910/162/03/23/0406

Issued by CTC, Notified Body N°0075, to the following model of personal protective equipment :

**Manufacturer :** OZBAY Is Guvenligi Malzemeleri San. ve Tic.Ltd.Sti  
Tersane Cad. 113/B Karakoy Istanbul  
Turkey

### Description

**PPE Type :** *protective glove against mechanical risks*

**Product reference :** H2-45H

**Article code :** /

**Glove description :** rough palm elbow sleeve heavy duty latex rubber glove

**Available sizes :** 10/(palm width113mm) 11/(palm width124mm)

**Pictures :**



Ozbay Is Guv. Mizm. San. Tic. Ltd. Sti.  
Tersane Cad. 113/B Karakoy Istanbul/Turkey  
Mfg Date: 20230222 Made in China

**Reference standard :**

**Levels of performance / class of protection**

**EN 420:2003+A1:2009**

-

**EN 388:2016 + A1:2018**

**3 1 1 0 X**

« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.

**At the date of certificate the product is in compliance with Annex XVII of REACh regulation (n° 1907/2006 and revisions)**

Full description of the PPE, reference rules verified in the context of the EU-type examination and information given on the product are detailed in the manufacturer's technical file and the Instruction for Use index 01 dated from MARCH 2023

NOTA : Any modification to new items of the personal protective equipment object of this EU type approval certificate or any modification of the information contained in the manufacturer technical file which served for the deliverance of the EU type approval certificate (change of address, change of company status) should be brought to the attention of the notified body in accordance with Annex V §7.2 of Regulation 2016/425. Any marking on the PPE which is not concerned by the Regulation (UE) 2016/425, is not covered by this certificate.

**Issued in Lyon by**  
Séverine AUBERT  
CE Expert Team Coordinator

**Date of first issue :** 13 March 2023  
**End of validity date :** 13 March 2028



In application of the Regulation 2016/425 of the European parliament and the Council of 9th March 2016 related to Personal Protective Equipment and repealing the Directive 89/686/EEC.



Accreditation n° 5-0594  
Scope available on:  
www.cofrac.fr

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Comité Professionnel de Développement Économique (CPDE) Cuir: Chaussure Maroquinerie Ganterie  
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**OZBAY Is Guvenligi Malzemeleri San. ve Tic.Ltd.Sti**

**MANUFACTURER'S TECHNICAL FILE TO THE  
PPE REGULATION 2016/425**

<b>Reference of the product</b>	<b>:</b>	<b>H2-45H</b>
<b>Article code</b>	<b>:</b>	<b>/</b>
<b>Technical file index</b>	<b>:</b>	<b>01</b>
<b>Last update</b>	<b>:</b>	<b>MARCH 2023</b>

## IDENTIFICATION

Reference of the product :	:	H2-45H
Article code :	:	/
Basic Model		
Technical file index :	:	01
Last update :	:	MARCH 2023

### **Manufacturer :**

OZBAY Is Guvenligi Malzemeleri San. ve Tic.Ltd.Sti

Tersane Cad. 113/B Karakoy Istanbul

Turkey

tel : 90 212 025 7749

fax : 90 212 235 9017

### **Factory :**

Yangjiang XingLi Rubber Products Co.Ltd

SHANG TA DONG WUFENG, YASHAO COUNTY, YANGDONG AREA, YANGJIANG,  
GUANGDONG

CHINA

tel: 0662 6793322

fax: 0662 6793336

## GLOVE DESCRIPTION

### General glove description :

rough palm elbow sleeve heavy duty latex rubber glove  
 type of coating finish : no coating

### Visual description (picture back and palm sides) :



### Field of use

against mechanical risks

Risk assessment (Essential Health and Safety Requirement. Annex II - PPE Regulation)			
		Applicable	Covered by
§1	Requirements defined in the Annex II §1 are applicable to all PPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§1.4	Manufacturer's instructions and information is available	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input type="checkbox"/> Marking
§2.4	If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§2.5	PPE which may be caught up during use	<input checked="" type="checkbox"/>	<input type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input type="checkbox"/> Marking
§2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§3.3	The PPE is intended to protect against mechanical injuries	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking

### Available sizes :

Minimum length of glove (mm)	Sizes
450	10/(palm width113mm)
450	11/(palm width124mm)

## **Glove constitution :**

	Reference	Color	Material	Surfacic mass	Gauges	Thickness
Palm	XL-2	black/orange (backing)	latex rubber			0.7mm
Back	XL-2	black/orange (backing)	latex rubber			0.7mm
Cuff	XL-2	black/orange (backing)	latex rubber			0.6mm
Binding	XL-3	orange(back of cuff)	latex rubber			

## **PROTECTION SCOPE**

This glove meets the essential requirements of the Personal Protective Equipment Regulation 2016/425.  
This glove is designed against mechanical risks.  
It is a category II product.

## **GENERAL REQUIREMENTS**

### **Standard EN 420 : 2003 + A1 : 2009**

Dexterity : 5

Size : conform

At the date of certificate the product is in compliance with Annex XVII of REACH regulation (n° 1907/2006 and revisions)

## **SPECIFIC REQUIREMENTS AND PERFORMANCE LEVELS**

### **Mechanical hazard EN 388 : 2016 + A1 : 2018**

<b>Protection offered</b>	<b>Performance levels</b>
Abrasion resistance	3
Blade cut resistance	1
Tear strength resistance	1
Puncture resistance	0
Cut Resistance method (EN ISO 13997)	X
Impact Protection	-

The levels of performance have been measured on the palm

« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.


## **TEST REPORTS**

Laboratory	CTC	Other
EN 420 + innocuousness	D170915454_1 ; D170915455_1 ; D130708778_1	
EN 388	D170915455_1	

## MARKING - PACKAGING

### **Information printed on the glove :**

Logo of Manufacturer :

Logo 

Glove's reference : H2-45H

Article Code : /

Size indicator

Pictograms related to risks against which protection is offered with performance levels

Information pictogram

Address of Manufacturer :

Date of Manufacture (month/year) and/or Serial number :

### **Marking example :**



### **Method of marking on the glove :**

PRINTING ON BACK

### **Packaging :**

1 pair/polybag, 72 pairs/carton

### **PPE subject to ageing :**

Peremption period : 5 years when stored in appropriate conditions (humidity, temperature, clean , ventilated, light). Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, ...).

### **Declaration of conformity :**

Available on : [www.ozbayis.com](http://www.ozbayis.com)

## MEANS OF CONTROL

1. We choose the good suppliers to provide us material with good quality. At the same time, when we received the each batch raw materials we should test some items according to relevant standard, such as EN 420 and relevant EU regulation; the bad material cannot meet requirement will be rejected.
2. When we received the raw materials for mass production every time, the material QC will check them serious to ensure they are of good quality.
3. Make samples before production, make sure samples meet the requirement of client and we test the glove as the requirement EN388, EN420, and other chemical items, then start to produce; it's very important for us;
4. Regular daily check the quality of products in the whole process; any unacceptable defects are found, the gloves will be discarded; QC for each step will perform inspection in accordance with our requirement strictly;
5. Confirm packing specification before packing and regularly check and keep records;
6. According to QA inspection procedures, QA will perform final inspection on some cartons of glove randomly. Then the goods can be shipped in case no any problems.
7. When do bulk production, we shall pick up some gloves from each batch to test abrasion and blade cut resistance of EN388, PAHs of latex to control the quality.

## INSTRUCTION FOR USE

OZBAY Is Guvenligi Malzemeleri San. ve Tic.Ltd.Sti

Tersane Cad. 113/B Karakoy Istanbul

Turkey

Glove reference : H2-45H

Article code: /

User notice index : 01

Last update : MARCH 2023

Available sizes : 10/(palm width113mm) 11/(palm width124mm)



Ozbay Is Guv. Mlzm. San. Tic. Ltd. Sti.  
Tersane Cad. 113/B Karakoy Istanbul/Turkey  
Mfg. Date: 20230222 Made in China

### **Glove description :**

rough palm elbow sleeve heavy duty latex rubber glove

THIS GLOVE IS A PERSONAL PROTECTIVE EQUIPMENT BELONGING TO THE CATEGORY II.

It meets the requirements of the PPE Regulation 2016/425 applicable from April 21th, 2018 : innocuousness, comfort, solidity.

It has been subject to a UE-type Examination performed by :

C.T.C. (OO75)  
4, rue Hermann Frenkel  
69367 LYON Cedex 07  
FRANCE

### **Applicable standards :**

The glove meets the requirements of the standard EN 420 : 2003 + A1 : 2009 « General requirements for work glove ». Dexterity : 5

Moreover, this glove has been designed for the following applications :

#### Application :

Mechanical hazard - EN 388 : 2016 +  
A1:2018



3 1 1 0 X

Levels of performance

Abrasion resistance	3	(on 4 maxi)
Blade cut resistance	1	(on 5 maxi)
Tear resistance	1	(on 4 maxi)
Puncture resistance	0	(on 4 maxi)
Cut Resistance method (EN ISO 13997)	X	(A to F)
Impact Protection		

« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.

### **Protection limit :**

Users should be warned that gloves should not be worn when there is a risk of entanglement by moving parts of machines.

This model does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health.

The protection against risks or hazards which are not mentioned in this document is not warranted.

The levels of performance mentioned are only valid for the palm of the glove.

The levels of performance mentioned are only valid for new gloves, not washed, nor regenerated.

These levels of performance are obtained from the tests done according to conditions defined by the applicable standards.

This glove shall not be in contact with fire

Contains natural rubber latex, which could cause allergic reaction, including anaphylactic choc.

Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, ...).

For gloves with different layers of material, the performance levels are warranted only for the whole glove.

For gloves with two or more layers the overall classification does not necessarily reflect the performance of the outermost layer.

### **Storage and cleaning notice**

Keep in its original packaging, under ordinary temperature and humidity conditions and in clean, covered and ventilated premises.

### **PPE subject to ageing :**

Peremption period : 5 years when stored in appropriate conditions (humidity, temperature, clean, ventilated, light). Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, ...).

### **Declaration of conformity :**

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