



# 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°** 0075/3246/162/12/19/3850

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

**Manufacturer :** Ergodyne Corporation  
1021 Bandana Boulevard East, Suite 220 Saint Paul, MN55108  
USA

## Description

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

**Product reference :** 7021

**Article code :** /

**Glove description :** 18G cut resistant liner, Nitrile + Water based PU palm coating

**Available sizes :** 7/S 8/M 9/L 10/XL 11/XXL

**Pictures :**



**Reference standard :**

**Levels of performance / class of protection**

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

-

**EN 388:2016**

**4 3 4 2 B**

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 DECEMBER 2019

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.

**Issued in Lyon by**  
**Didier GUISADO**  
Certification and Quality Manager

**Date of first issue :** 30 December 2019  
**End of validity date :** 30 December 2024



Original CTC



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.

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## Ergodyne Corporation

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

Reference of the product	:	7021
Article code	:	/
Technical file index	:	01
Last update	:	DECEMBER 2019

## IDENTIFICATION

Reference of the product :	:	7021
Article code :	:	/
Basic Model		
Technical file index :	:	01
Last update :	:	DECEMBER 2019

### **Manufacturer :**

Ergodyne Corporation  
1021 Bandana Boulevard East, Suite 220 Saint Paul, MN55108  
USA  
tel : + 001 651 642 9889  
fax :

### **Factory :**

Huihong (Nantong) Safety Products Co.,Ltd  
NO. 98 Huaihe Road Rudong New Development Zone Nantong City Jiangsu Province  
China  
tel: + 0086 513 8453 6066  
fax: + 0086 513 8412 9009

## GLOVE DESCRIPTION

### General glove description :

18G cut resistant liner, Nitrile + Water based PU palm coating  
type of coating finish : sandy

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



### Field of use

Assembly and small parts handling, logistics and warehousing, maintenance, using tools and instruments

#### 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 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 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
230	7/S
240	8/M
250	9/L
260	10/XL
270	11/XXL

## **Glove constitution :**

	Reference	Color	Material	Surfacic mass (g/m <sup>2</sup> )	Gauges	Thickness
Palm		black	Nitrile + Water based PU			0.4mm
		Lime	HPPE(high performance polyethylene)+glass fiber	278g/m2	18	
Back		Lime	HPPE(high performance polyethylene)+glass fiber	278g/m2	18	
Cuff		Lime/White	HPPE(high performance polyethylene)+glass fiber+elastic	448g/m2	18	
Binding		yellow, grey, orange, black, white	polyester			

## **PROTECTION SCOPE**

This glove meets the essential requirements of the Personal Protective Equipment Regulation 2016/425.  
This glove is designed for 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**

Protection offered	Performance levels
Abrasion resistance	4
Blade cut resistance	3
Tear strength resistance	4
Puncture resistance	2
Cut Resistance method (EN ISO 13997)	B
Impact Protection	-

The levels of performance have been measured on the palm


## TEST REPORTS

Laboratory	CTC	Other
EN 420 + innocuousness	S190201601_1 S150705522_1 S160403212_1 S180608339_1 S190302412_1(DMFu)	
EN 388	S190201604_1 S190201605_1 S190201606_1 S190201607_1 S190201603_1	
Other	S190201602_1	

## MARKING - PACKAGING

### Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : 7021

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 :

heat transfer

### Packaging :

12 pairs per polybag, 144 pairs per 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 with product.

## MEANS OF CONTROL

According to ISO 9001, we checked every batch of sampling for abrasion resistance under EN388:2016 every 2 months.



## INSTRUCTION FOR USE

### Ergodyne Corporation

1021 Bandana Boulevard East, Suite 220 Saint Paul, MN55108  
USA

Glove reference : 7021

Article code: /

User notice index : 01

Last Update : DECEMBER 2019

Available sizes : 7/S 8/M 9/L 10/XL 11/XXL



### Glove description :

18G cut resistant liner, Nitrile + Water based PU palm coating

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. (0075)  
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



4 3 4 2 B

Levels of performance

Abrasion resistance	4	(on 4 maxi)
Blade cut resistance	3	(on 5 maxi)
Tear resistance	4	(on 4 maxi)
Puncture resistance	2	(on 4 maxi)
Cut Resistance method (EN ISO 13997)	B	(A to F)
Impact Protection		

### 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

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.

For dulling during the cut resistance test, the coupe test results are only indicative while the TDM cut resistance test is the reference performance result.

### 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 :

Available with product.