



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° 0075/3246/162/12/19/3851

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 : 7001
Article code : /
Glove description : 18G nylon+spandex liner, foam nitrile + PUD 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 1 2 1 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 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 delivrance 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.

www.ctcgroupe.com

cemarking@ctcgroupe.com

CTC - 4, rue Hermann Frenkel - 69367 Lyon cedex 07 - France
Tél. : +33 (0)4 72 76 10 10 - Fax : +33 (0)4 72 76 10 00 - ctclyon@ctcgroupe.com

Comité Professionnel de Développement Économique (CPDE) Cuir Chaussure Maroquinerie Ganterie
Loi 78-654 du 22.06.1978 - Siret 77564972600160 - Code NAF 9412Z - TVA FR 88775649726

Ergodyne Corporation

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

Reference of the product	:	7001
Article code	:	/
Technical file index	:	01
Last update	:	DECEMBER 2019

IDENTIFICATION

Reference of the product :	:	7001
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 nylon+spandex liner, foam nitrile + PUD palm coating
type of coating finish : foam

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

Glove constitution :

	Reference	Color	Material	Surfacic mass (g/m ²)	Gauges	Thickness
Palm		black	nitrile+PUD			0.25mm
		black	nylon+spandex	164g/m ²	18	
Back		black	nylon+spandex	164g/m ²	18	
Cuff		black	nylon+spandex/elastic	280g/m ²	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	1
Tear strength resistance	2
Puncture resistance	1
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	S190302329_1 S190100571_1 S150705522_1 S160403212_1 S180608339_1 S190302412_1(DMFu)	
EN 388	S190302329_1 S190100573_1 S190100574_1 S190100575_1	

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : 7001

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 : 7001

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 nylon+spandex liner, foam nitrile + PUD 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. (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



4 1 2 1 X
Levels of performance

Abrasion resistance	4	(on 4 maxi)
Blade cut resistance	1	(on 5 maxi)
Tear resistance	2	(on 4 maxi)
Puncture resistance	1	(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

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 :

Available with product.