



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° 0075/631/162/10/20/2504

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

Manufacturer : OX-ON A/S
Egelund 23,6200 Aabenraa
Denmark

Description

PPE Type : *protective glove against mechanical risks*
Product reference : Flexible Comfort 1305
Article code : 91247, 91248, 91249, 91250, 91251
Glove description : nylon knitted liner coated with micro foam nitrile gloves
Available sizes : 7/S(91247) ,8/M(91248), 9/L(91249), 10/XL(91250), 11/XXL(91251)
Pictures :



Flexible
Comfort 1305

7
S
91247

EN388:2016
4121X

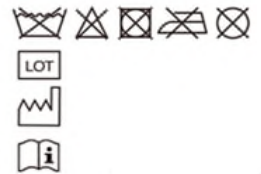
CE CAT. II



Nylon
Nitrile
Elastan

OX-ON A/S
Egelund 23
6200 Aabenraa
Denmark

www.ox-on.com/docs



Reference standard :

Levels of performance / class of 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.
« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

EN ISO 21420:2020

-

EN 388:2016 + A1:2018

4 1 2 1 X

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 OCTOBER 2020

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
Maxence DREVET
Project Certification Manager

Date of first issue : 13 October 2020
End of validity date : 13 October 2025



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:
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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

OX-ON A/S

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

Reference of the product	:	Flexible Comfort 1305
Article code	:	91247, 91248, 91249, 91250, 91251
Technical file index	:	01
Last update	:	OCTOBER 2020

IDENTIFICATION

Reference of the product :	:	Flexible Comfort 1305
Article code :	:	91247, 91248, 91249, 91250, 91251
Basic Model		
Technical file index :	:	01
Last update :	:	OCTOBER 2020

Manufacturer :

OX-ON A/S

Egelund 23,6200 Aabenraa

Denmark

tel : +45 7431 1682

fax : +45 5158 1682

Factory :

PERFECT ROBERT'S (TAI HE XIAN) INDUSTRIAL LTD.

WENTIAN INDUSTRIAL PARK, TAIHE, JIANGXI PROVINCE

P.R. CHINA

tel: +86 796 5376001

fax: +86 796 5376002

GLOVE DESCRIPTION

General glove description :

nylon knitted liner coated with micro foam nitrile gloves

This glove is designed against mechanical risks.

Type of coating finish: foam

Visual description (picture back and palm sides) :



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
§2.5	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

Glove constitution :

	Reference	Color	Material	Surfacic mass (g/m ²)	Gauges	Thickness
Palm		black	nitrile			1mm
		grey	nylon	500g/m ²	15 gauge	
Back		grey	nylon	500g/m ²	15 gauge	
Cuff		grey	nylon/elastic	550g/m ²	15 gauge	
Binding		black/red	nylon			

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 ISO 21420:2020

Dexterity : 5

Available size range: 7/S(91247) ,8/M(91248), 9/L(91249), 10/XL(91250), 11/XXL(91251)

The hand sizing system is based on hand circumference and hand length as defined in EN ISO 21420 Annex B table B.1

SPECIFIC REQUIREMENTS AND PERFORMANCE LEVELS

« 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.

« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

Mechanical hazard EN 388 : 2016 + A1 : 2018

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

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S200606016_3 S161213793_1 S161213795_1 S200505477_1(DMFU)	
EN 388	S200606016_3	

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : Flexible Comfort 1305

Article Code : 91247, 91248, 91249, 91250, 91251

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/batch number :

Date of obsolescence (month/year) if applicable:

Marking example :



Method of marking on the glove :

silk screen or heat transfer printing logo on the back of gloves

Packaging :

12 pairs/polybag, 144 pairs/carton.

PPE subject to ageing :

The design performance can not be significantly affect by ageing when stored in appropriate conditions (humidity, temperature, clean , ventilated, light).

Cleaning:

The gloves are not washable.

MEANS OF CONTROL

We control the quality as per follow:

1. All materials incoming should be inspected by Incoming Quality Control department. Any change of materials should be confirmed by engineering department after passed the test (Normally we use the materials to make some sample and test these samples for the abrasion, cutting, tear and puncture resistance, if there are any unconformity with the original sample, the materials will be rejected).
2. Engineering department design the working instruction for every working station of knitting, dipping and packing, the instructions should be made according to EN standard and client's requirements; all workers should be work as per these instructions.
3. The first sample should be approved by manager of factory before begin production for every order.
4. We'll spot-check the weight of glove shell and measure the length, width of gloves after knitting. any unconformity against the instruction will be fed back to technician who will adjust the knitting machine.
5. We'll spot-check the size and test the abrasion, cutting, tear and puncture resistance of gloves during and after dipping process, any unconformity against the instruction will be fed back to technician who will improve the process through adjust temperature, speed and formular of coating liquid.
6. The formula of coating should be strictly stable, we check it three times per day.
7. Packing: production department should make the first sample of packing and send it to Manager for approval, Quality Control department will spot-check them before and after production.
8. All products should be inspected strictly before outgoing.
9. we'll send the samples to CTC Asia to re-test the EN388 two times per year.

INSTRUCTION FOR USE

OX-ON A/S

Egelund 23,6200 Aabenraa

Denmark

Glove reference : Flexible Comfort 1305

Article code: 91247, 91248, 91249, 91250, 91251

User notice index : 01

Last update : OCTOBER 2020

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LOT



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Flexible
Comfort 1305



91247

EN388:2016



4121X

CE CAT. II



Glove description :

nylon knitted liner coated with micro foam nitrile gloves

This 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 ISO 21420 : 2020 « Protective Gloves - General requirements and test methods ».

Dexterity: 5

Available Size Range: 7/S(91247) ,8/M(91248), 9/L(91249), 10/XL(91250), 11/XXL(91251)

The hand sizing system is based on hand circumference and hand length as defined in EN ISO 21420 Annex B.

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

« 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.

« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

Application :

Mechanical hazard - EN 388:2016 +
A1:2018



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		

Read carefully the instructions for use provided with the product

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 .

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

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

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

No flame protection is claimed. This glove shall not be in contact with naked flame.

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

The levels of performance against mechanical risks mentioned are only valid for the palm of the glove (except Impact protection).

Storage and cleaning notice

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

Cleaning instructions : The gloves are not washable.

PPE subject to ageing :

The design performance can not be significantly affect by ageing when stored in appropriate conditions (humidity, temperature, clean , ventilated, light).

Declaration of conformity :

Available with product.