



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° **0075/2901/162/08/22/1509**

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

Manufacturer : **Optimera AS**
Østre Akervei 260, 0976 Oslo
Norway

Description

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

Product reference : **7557811, 7557812, 7557813**

Article code : **/**

Glove description : **15G spandex plus nylon liner with nitrile micro foam palm coated**

Available sizes : **9/L (7557811), 10/XL (7557812), 11/XXL (7557813)**

Pictures :



Østre Akervei 260, 0976 Oslo, Norway



Optimera AS

Art.7557813

Size.11 XX- Large

EN388:2016
+A1:2018



Cat. II



4131X



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 3 1 X

At the date of the 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 AUGUST 2022

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
Didier GUISADO
Certification Manager

Date of first issue : 16 August 2022
End of validity date : 16 August 2027



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

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

Optimera AS

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

Reference of the product	:	7557811, 7557812, 7557813
Article code	:	/
Technical file index	:	01
Last update	:	AUGUST 2022

IDENTIFICATION

Reference of the product :	:	7557811, 7557812, 7557813
Article code :	:	/
Basic Model		
Technical file index :	:	01
Last update :	:	AUGUST 2022

Manufacturer :

Optimera AS

Østre Akervei 260, 0976 Oslo

Norway

tel : +47 22168800

fax : +47 22168800

Factory :

Jiangsu Hanvo Safety Product Co., Ltd

HUANGSHAN ROAD,RUDONG NEW DEVELOPMENT ZONE,RUDONG
COUNTY,JIANGSU

CHINA

tel: 0086-513-81907309

fax: 0086-513-84536318

GLOVE DESCRIPTION

General glove description and intended use:

15G spandex plus nylon liner with nitrile micro foam palm coated

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 checked="" 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			0.3mm
		grey	spandex/ nylon	225g/m ²	15G	
Back		grey	spandex/ nylon	225g/m ²	15G	
Cuff		grey/ white	spandex/ nylon/ elastics	280g/m ²	15G	
Binding		yellow/ white/ light blue	polyester			

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: 9/L (7557811), 10/XL (7557812), 11/XXL (7557813)

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	3
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	S200808139_1 S210100807_1 S200301432_1 S210908604_1 (DMFu)	
EN 388	S200808139_1 S201010612_1	

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : 7557811, 7557812, 7557813

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/batch number :

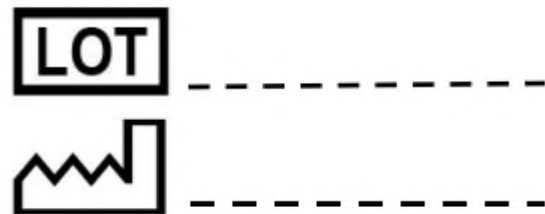
Date of obsolescence (month/year) if applicable:

Marking example :

Optimera AS
Art.7557813
Size.11 XX- Large
EN388:2016
+A1:2018

Cat. II 4131X



Østre Akervei 260, 0976 Oslo, Norway

Method of marking on the glove :

printing on the back

Packaging suitable for transport:

1 pairs per hantag , 12 pairs in the poly bag, 120 pairs in box

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 instructions:

The gloves are not washable.

MEANS OF CONTROL

Firstly, IQC will take sample to monitor (ISO 2859, G1) the knitting gloves performance. They check the gloves on hand former, and monitor the glove color, total length, weight, visual defect Ext. If find abnormal will follow the non-conforming procedure to handle it.

Then, IPQC will check the product after dipping, they will check the total length, palm width, weight, and monitor the visual defects and performance, example: taste, dipping position Ext.

The next is packing process, QA will monitor the logo, bag, carton, label Ext. If ok, the glove will be send to warehouse.

In warehouse, FQC will check the final product.

This is a strict monitor procedure. We pick out the defects around 2%-4% in this process. We can ensure the quality according it.

Then, we will ship the gloves to our customer site.

For EN388 test, we have been certified by CTC, we have test machine in our laboratory. When we beginning a new order, we will test the gloves firstly. We also have the testing regularly during the production process. The testing includes abrasion(test every one year), cut, tear, puncture.

For EN ISO 21420 test, we asked our vendor to according to the request, and they cannot use any materials which contain Hazardous Substances. For each style, we send the final gloves to third party to monitor it regularly

INSTRUCTION FOR USE

Optimera AS

Østre Akervei 260, 0976 Oslo

Norway

Glove reference : 7557811, 7557812, 7557813

Article code: /

User notice index : 01

Last update : AUGUST 2022

Glove description :

15G spandex plus nylon liner with nitrile micro foam palm coated

This glove is a personal protective equipment belonging to the category II.

It meets the requirements of the PPE Regulation 2016/425 : 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

Optimera AS

Art.7557813

Size.11 XX- Large

EN388:2016
+A1:2018



Cat. II

4131X

LOT



Østre Akervei 260, 0976 Oslo, Norway

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: 9/L (7557811), 10/XL (7557812), 11/XXL (7557813)

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



Read carefully the instructions for use provided with the product



4 1 3 1 X

Levels of performance

Abrasion resistance	4	(on 4 maxi)
Blade cut resistance	1	(on 5 maxi)
Tear resistance	3	(on 4 maxi)
Puncture resistance	1	(on 4 maxi)
Cut Resistance method (EN ISO 13997)	X	(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.

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 inspected for any defect or imperfections. 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 are only valid for the palm of the glove.

Storage and cleaning notice

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

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.

Available on : www.monter.no