



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° 0075/4207/162/01/21/0015

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

Manufacturer : SECURE(NINGBO) INDUSTRIAL TECHNOLOGY CO.,LTD
ROOM 810 AIYIMEI BUILDING, NO.756 TIAN TONG NAN ROAD, NINGBO
ZHEJIANG
China

Description

PPE Type : *protective glove against microorganisms risks*

Product reference : SECBS1121

Article code :

Glove description : Disposable Nitrile Gloves

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

Pictures :



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 ISO 374-5:2016

MICRO-ORGANISMS

This glove is intended to activity that does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent.

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 JANUARY 2021

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 GUISSADO

Certification and Quality Manager

Date of first issue : 07 January 2021

End of validity date : 07 January 2026



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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www.ctcgroupe.com

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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

SECURE(NINGBO) INDUSTRIAL TECHNOLOGY CO.,LTD

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

Reference of the product	:	SECBS1121
Article code	:	
Technical file index	:	01
Last update	:	JANUARY 2021

IDENTIFICATION

Reference of the product :	:	SECBS1121
Article code :	:	
Basic Model		
Technical file index :	:	01
Last update :	:	JANUARY 2021

Manufacturer :

SECURE(NINGBO) INDUSTRIAL TECHNOLOGY CO.,LTD

ROOM 810 AIYIMEI BUILDING, NO.756 TIAN TONG NAN ROAD, NINGBO ZHEJIANG

China

tel : 13857854761

fax : 057488255842

Factory :

SECURE(NINGBO) INDUSTRIAL TECHNOLOGY CO.,LTD

ROOM 810 AIYIMEI BUILDING, NO.756 TIAN TONG NAN ROAD, NINGBO ZHEJIANG

China

tel: 13857854761

fax: 057488255842

GLOVE DESCRIPTION

General glove description and intended use:

Disposable Nitrile Gloves

This glove is designed against microorganisms risks .

This glove is intended to activity that does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent.

Type of coating finish : no coating

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

Glove constitution :

	Reference	Color	Material	Surfacic mass (g/m ²)	Gauges	Thickness
Palm		blue	nitrile			0.08mm
Back		blue	nitrile			0.08mm
Cuff		blue	nitrile			0.08mm

PROTECTION SCOPE

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

GENERAL REQUIREMENTS

Standard EN ISO 21420 : 2020

Dexterity : 5
Available size range: 7/S-10/XL

A different hand sizing system from the one defined in EN ISO 21420 Annex B table B.1 is used:

Hand size	Hand circumference (mm)	Hand length (mm)
7/S	170MM	161MM
8/M	190MM	168MM
9/L	210MM	175MM
10/XL	230MM	183MM

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.

Microorganism EN ISO 374-5 : 2016

This glove protect against microorganism.

The glove shall be used in following conditions :

Work place or similar :

- Work in food production plants
- Work in agriculture.
- Work activities where there is contact with animals and/or products of animal origin.
- Work in healthcare, including isolation and post-mortem units.
- Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
- Work in refuse disposal plants
- Work in sewage purification installations

The activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent

Uncontrolled against viruses.

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S201011014_1	
EN ISO 374-5	S201011014_1	

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : SECBS1121

Article Code :

Size indicator

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

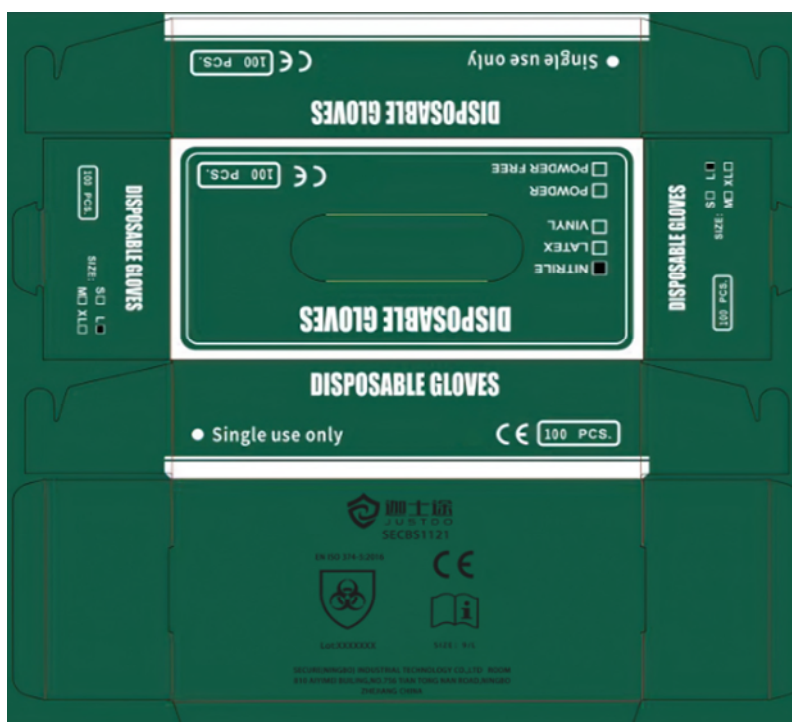
Information pictogram

Address of Manufacturer :

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

Date of obsolescence (month/year) if applicable:

Marking of packaging example :



Method of marking on the glove :

Print on the box

Packaging suitable for transport:

100 pcs per box, 1000 pcs per 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 instructions:

The gloves are not washable.

MEANS OF CONTROL

1. According to certain chemical standard, we test and check the raw material before we accept them from our supplier, we keep the material at proper place and condition, marked available date and code of supplier.
2. Mainly we check the raw material for every batch. We put them at the certain place in warehouse.
3. For coating, packing precessing, every step check the last step, signing the name of the last one.
4. We do a simple and tested by a competent laboratory CTC Shanghai as per Air leak & Water leak testing every one month. If the test result compliance with the relevant standards and reach to our requirement, we will produce mass production same as the samples, and check at least 2% of total quantity before shipment.

INSTRUCTION FOR USE

SECURE(NINGBO) INDUSTRIAL TECHNOLOGY CO.,LTD

ROOM 810 AIYIMEI BUILDING, NO.756 TIAN TONG NAN ROAD, NINGBO ZHEJIANG

China

Glove reference : SECBS1121

Article code:

User notice index : 01

Last update : JANUARY 2021

Glove description :

Disposable Nitrile Gloves

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



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-10/XL

A different hand sizing system from the one defined in EN ISO 21420 Annex B is used:

Hand size	Hand circumference (mm)	Hand length (mm)
7/S	170MM	161MM
8/M	190MM	168MM
9/L	210MM	175MM
10/XL	230MM	183MM

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 :

Microorganism - EN ISO 374-5 : 2016



Microorganism resistant

Conform



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.

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.

The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

The glove shall be used in following conditions :

Work place or similar :

- *Work in food production plants*
- *Work in agriculture.*
- *Work activities where there is contact with animals and/or products of animal origin.*
- *Work in healthcare, including isolation and post-mortem units.*
- *Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.*
- *Work in refuse disposal plants*
- *Work in sewage purification installations*

The activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent.

Uncontrolled against viruses.

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.skgloves.en.alibaba.com