



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° 0075/1462/162/07/20/2041

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

Manufacturer : **Wuxi Fangqian Plastic Working Glove Co., Ltd.**
A3-9, No.777 West of Jianzhu Road, Circuit Industrial Park, Wuxi, JS, 214073 China

Description

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

Product reference : **FQ-34001, FQ-34001-BE, FQ-34001-BK**

Article code : **/**

Glove description : **Vinyl disposable glove**

Available sizes : **S M L XL**

Pictures :



Reference standard :

EN ISO 21420:2020

EN ISO 374-5:2016

Levels of performance / class of protection

MICRO-ORGANISMS

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 JULY, 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 : 23 July 2020
End of validity date : 23 July 2025



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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

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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

Wuxi Fangqian Plastic Working Glove Co., Ltd.

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

Reference of the product	:	FQ-34001, FQ-34001-BE, FQ-34001-BK
Article code	:	/
Technical file index	:	01
Last update	:	JULY, 2020

IDENTIFICATION

Reference of the product :	:	FQ-34001, FQ-34001-BE, FQ-34001-BK
Article code :	:	/
Basic Model	:	
Technical file index :	:	01
Last update :	:	JULY, 2020

Manufacturer :

Wuxi Fangqian Plastic Working Glove Co., Ltd.
A3-9, No.777 West of Jianzhu Road, Circuit Industrial Park, Wuxi, JS, 214073
China

tel : +86-510-85164102
fax : +86-510-85160302

Factory :

Wuxi Fangqian Plastic Working Glove Co., Ltd.
A3-9, No.777 West of Jianzhu Road, Circuit Industrial Park, Wuxi, JS, 214073
China

tel: +86-510-85164102
fax: +86-510-85160302

GLOVE DESCRIPTION

General glove description :

Vinyl disposable glove

This glove is designed against microorganisms risks .

type of coating finish : no coating

Visual description (picture back and palm sides) :



FQ-34001



FQ-34001-BE



FQ-34001-BK

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 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 type="checkbox"/> Instruction for use <input checked="" 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 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 type="checkbox"/> Instruction for use <input checked="" 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 type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking

Glove constitution :

	Reference	Color	Material	Surfacic mass	Gauges	Thickness
Palm	FQ-VI-01	TRANSPARENT , BLUE, BLACK	VINYL			3mm
Back	FQ-VI-01	TRANSPARENT , BLUE, BLACK	VINYL			3mm
Cuff	FQ-VI-01	TRANSPARENT , BLUE, BLACK	VINYL			3mm

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: S; M; L; 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)
S	160	160
M	180	171
L	200	182
XL	220	192

SPECIFIC REQUIREMENTS AND PERFORMANCE LEVELS

Microorganism EN ISO 374-5 : 2016

This glove protect against microorganism

Uncontrolled against viruses

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	D200609332_1; D200609333_1; D200609334_2; D191225111_1	
EN ISO 374-5	D200609333_1	

MARKING - PACKAGING

Information printed on the box :

Logo of Manufacturer :

Logo 

Glove's reference : FQ-34001, FQ-34001-BE, FQ-34001-BK

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 of packaging example :



Method of marking on the box :

Printing on the box

Packaging :

100PC/BOX, 10BOXES/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, ...).

MEANS OF CONTROL

1. We choose the good suppliers to provide us material with good quality. At the same time, when we received the each batch raw materials we should test some items according to relevant standard, such as EN ISO 21420 and relevant EU regulation; the bad material cannot meet requirement will be rejected.
2. when we received the raw materials for mass production every time, the material QC will check them serious to ensure they are of good quality.
3. Make samples before production, make sure samples meet the requirement of client and we test the glove as the requirement EN ISO 21420, and other chemical items,then start to produce; it's very important for us;
4. Regular daily check the quality of products in the whole process; any unacceptable defects are found, the gloves will be discarded; QC for each step will perform inspection in accordance with our requirement strictly;
5. Confirm packing specification before packing and regularly check and keep records;
6. According to QA inspection procedures, QA will perform final inspection on some cartons of glove randomly. Then the goods can be shipped in case no any problems.
7. When do bulk production, we shall pick up some gloves from each batch to test Air tightness of EN ISO 374-5 and PAHs of vinyl to control the quality.

INSTRUCTION FOR USE

Wuxi Fangqian Plastic Working Glove Co., Ltd.

A3-9, No.777 West of Jianzhu Road, Circuit Industrial Park, Wuxi, JS, 214073
China

Glove reference : FQ-34001, FQ-34001-BE, FQ-34001-BK

Article code: /

User notice index : 01

Last update : JULY, 2020



Glove description :

Vinyl disposable glove

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

Dexterity: 5

Available Size Range: 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)
S	160	160
M	180	171
L	200	182
XL	220	192

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

Application :

Microorganism - EN ISO 374-5 : 2016



Microorganism resistant

Conform

Conform

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.

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

This glove shall not be in contact with fire.

For gloves with different layers of material, the performance levels are warranted only for the whole glove.

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

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.

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.