



# 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° 0075/4184/162/04/21/0677**

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

**Manufacturer :**

### Description

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

**Product reference :** **Gug 0101**

**Article code :** /

**Glove description :** **Disposable Nitrile gloves**

**Available sizes :** **6/S 7/M 8/L 9/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**

**EN ISO 374-1:2016 / A1:2018**

**Type C**

**K**

This product is a category III (lethal or irreversible risk). This certificate shall only be used in conjuncture with the conformity assessment procedure according to module C2 (CTC 0075)

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 APRIL, 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.

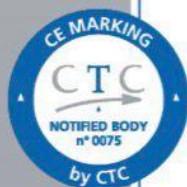
**Issued in Lyon by**

**Date of first issue : 15 April 2021**

**Didier GUISADO**

**End of validity date : 15 April 2026**

**Certification and Quality Manager**



Accreditation n° 5-0594  
Scope available on:  
www.cofrac.fr

[www.ctcgroupe.com](http://www.ctcgroupe.com)

[cemarking@ctcgroupe.com](mailto: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](mailto: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

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

<b>Reference of the product</b>	:	<b>Gug 0101</b>
<b>Article code</b>	:	<b>/</b>
<b>Technical file index</b>	:	<b>01</b>
<b>Last update</b>	:	<b>APRIL, 2021</b>

## IDENTIFICATION

Reference of the product :	:	Gug 0101
Article code :	:	/
Basic Model		
Technical file index :	:	01
Last update :	:	APRIL, 2021

### **Manufacturer :**

China

tel :

fax :

### **Factory :**

## GLOVE DESCRIPTION

### General glove description :

Disposable Nitrile gloves

This glove is designed against chemical risks , microorganisms risks.

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
§2.4	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 checked="" 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
§2.14	Multi-risk PPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§3.10.2	PPE intended to protect against substances and mixtures which are hazardous to health and against harmful biological agents - Cutaneous contact	<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 <sup>2</sup> )	Gauges	Thickness
Palm		Blue	Nitrile			0.1mm
Back		Blue	Nitrile			0.1mm
Cuff		Blue	Nitrile			0.1mm

## **PROTECTION SCOPE**

This glove meets the essential requirements of the Personal Protective Equipment Regulation 2016/425.

This glove is designed against chemical risks , microorganisms risks.

It is a category III product, module C2

Notified Body Reference : CTC (0075)  
Parc Scientifique Tony Garnier, 4, rue Hermann Frenkel-  
69367 Lyon Cedex 07-France

## **GENERAL REQUIREMENTS**

### **Standard EN ISO 21420:2020**

Dexterity : 5

Available size range: 6/S - 9/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)
6/S	85	165
7/M	95	172
8/L	105	185
9/XL	115	193

## **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.

### **Chemical hazard EN 374-2 : 2014**

Protection offered	Performance levels
Water tightness	conform
Air tightness	conform

### **Chemical hazard EN ISO 374-1:2016 + A1:2018**

<b>Type :</b>	Type C
---------------	--------

Tested chemical :	CAS N°	Letter	Permeation performance levels:	Degradation value:
Sodium hydroxide 40%	1310-73-2	K	6	-15,4%

## Microorganism EN ISO 374-5:2016

This glove protect against microorganism.  
Uncontrolled against viruses.


### TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S200909121_2 S210100272_2 S200909118_2 (DMFu)	
EN 374-2	S200909121_2	
EN 16523-1	S210100272_2	
EN ISO 374-5	S200909121_2	
Other	S210100272_2 (EN374-4)	

### MARKING - PACKAGING

#### Information printed on the box :

Logo of Manufacturer :

Logo 

Glove's reference : Gug 0101

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 :



## **Marking of packaging example :**



## **Method of marking on the glove :**

Print on the box

## **Packaging :**

50 Pairs / boxes, 10 boxes / big box ; Box Gauge: 32 \* 25 \* 25cm

## **PPE subject to ageing :**

Peremption period : 2 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, ...).

## **Cleaning:**

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 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.