



# 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°**            **0075/2095/162/06/21/1083**

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

**Manufacturer :**            **Kupfer Hermanos S.A**  
Libertad #54, 8350635, Santiago  
CHILE

**Description**

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

**Product reference :**        **D5000**

**Glove description :**        **Disposable nitrile glove**

**Available sizes :**            **6/XS 7/S 8/M 9/L 10/XL 11/XXL 12/XXXL**

**Pictures :**



Libertad #54, 8350635  
Santiago  
CHILE

MOD. D5000 - Size 9/L

XX/XX/XXXX



LOT : XXXX

**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**

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**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 JUNE 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 GUISADO**  
Certification and Quality Manager

**Date of first issue :** 24 June 2021  
**End of validity date :** 24 June 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:  
www.cofrac.fr

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

## Kupfer Hermanos S.A

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

Reference of the product	:	D5000
Article code	:	
Technical file index	:	01
Last update	:	JUNE 2021

## IDENTIFICATION

Reference of the product :	:	D5000
Article code :	:	
Basic Model		
Technical file index :	:	01
Last update :	:	JUNE 2021

### **Manufacturer :**

Kupfer Hermanos S.A

Libertad #54, 8350635, Santiago

CHILE

tel : 56 2 2351 5154

### **Factory :**

SHANDONG XINGYU GLOVES CO.,LTD

MIDDLE YAOQIAN ROAD CHAOYANG DISTRICT GAOMI CITY SHANDONG  
PROVINCE

CHINA

tel: 0086-536-2587338

fax: 0086-536-2586328

## GLOVE DESCRIPTION

### General glove description and intended use:

Disposable nitrile glove

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
§2.4	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
§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			0.2mm
Back		blue	nitrile			0.2mm
Cuff		blue	nitrile			0.2mm

## **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: 6/XS,7/S,8/M,9/L,10/XL,11/XXL,12/XXXL

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/XS	152	160
7/S	178	171
8/M	203	182
9/L	229	192
10/XL	254	204
11/XXL	279	215
12/XXXL	282	226

## **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	S200301781_1 S200909432_1 S200807857_1 (DMFu)	
EN ISO 374-5	S200909432_1	

## MARKING - PACKAGING

### Information printed on the glove :

Logo of Manufacturer :

Logo

Glove's reference : D5000

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 :

ink printing on the box

## Packaging suitable for transport:

100pieces/BOX

## PPE subject to ageing :

Peremption period : 3 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 instructions:

The gloves are not washable.

## MEANS OF CONTROL

According to ISO 9001, random inspect EN374-2 air leak & water leak for every batch



## INSTRUCTION FOR USE

### Kupfer Hermanos S.A

Libertad #54, 8350635, Santiago

CHILE

Glove reference : D5000

Article code:

User notice index : 01

Last update : JUNE 2021



### **Glove description :**

Disposable nitrile glove

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: 6/XS,7/S,8/M,9/L,10/XL,11/XXL,12/XXXL

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)
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7/S	178	171
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9/L	229	192
10/XL	254	204
11/XXL	279	215
12/XXXL	282	226

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
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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.*

*Contains natural rubber latex, which could cause allergic reactions, including anaphylactic choc.*

*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 :**

*Peremption period : 3 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.*