

DECLARACIÓN UE CONFORMIDAD

Distribuidor: JBM CAMPLLONG, S.L.U.

Dirección: CIM La Selva – Crta. Aeroport Km 1.6 Nave 2.2, 17185 Vilobí d'Onyar

CIF: B17419292

Descripción del producto: Guantes desechables de nitrilo

Referencia del fabricante: SQKC003

Referencia del distribuidor: 53923, 53924, 53925, 53926

El objeto de la declaración es conforme al Reglamento (UE) 2016/425 relativo a los Equipos de protección individual y a las siguientes normas:

Norma	Título	Edición/Fecha
EN ISO 21420	Guantes de protección. Requisitos generales y métodos de ensayo.	2020
EN ISO 374-1	Guantes de protección contra los productos químicos y los microorganismos. Parte 1: Terminología y requisitos de prestaciones.	2016
EN ISO 374-2	Guantes de protección contra los productos químicos y los microorganismos. Parte 2: Determinación de la resistencia a la penetración.	2019
EN ISO 374-5	Guantes de protección contra los productos químicos y los microorganismos peligrosos. Parte 5: Terminología y requisitos de prestaciones para riesgos por microorganismos.	2016
ISO 3071	Textiles. Determinación del pH del extracto acuoso.	2020
ISO 14362-1	Textiles. Métodos para la determinación de ciertas aminas aromáticas derivadas de colorantes azoicos. Parte 1: Detección del uso de ciertos colorantes azoicos accesibles con y sin extracción de fibras.	2017
ISO/TS 16190	Calzado. Sustancias críticas potencialmente presentes en calzado y componentes de calzado. Método de ensayo para la determinación cuantitativa de hidrocarburos cíclicos aromáticos (PAH) en materiales de calzado.	2013
CEN ISO TS 1618	• •	2011

Certificado CE realizado por:

C.T.C.

Nº organismo notificado: 0075

4, rue Hermann Frenkel

69367 Lyon Cedex 07 - France

No. de certificado: 0075/4129/162/09/20/2390

Nº test report: S201010886_1, S200807888_1

Firmado:



Eduard Godoy

Director departamento de compras

En Girona, a 17 de noviembre de 2020



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° 0075/4129/162/09/20/2390

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

Manufacturer: Shenzhen Shigiao Science and Technology Co.LTD

B2904, Nanshan Software Park, No.10128, Shennan Avenue, Liancheng

Community, Nantou Street, Nanshan District, Shenzhen City

China

Description

PPE Type: protective glove against microorganisms risks

Product reference: SQKC003

Article code:

Glove description: **Disposable Nitrile Gloves**

8/M 9/L 10X/L **Available sizes:**

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

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 SEPTEMBER 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

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.

Date of first issue: 16 September 2020 End of validity date: 16 September 2025





www.ctcgroupe.com

cemarking@ctcgroupe.com

cofrac Accreditation n# 5-0594 Scope available on:

www.cofrac.fr

Shenzhen Shiqiao Science and Technology Co.LTD

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

Reference of the product : SQKC003

Article code :

Technical file index : 01

Last update : SEPTEMBER 2020

IDENTIFICATION

Reference of the product: : SQKC003

Article code :

Basic Model

Technical file index: : 01

Last update : : SEPTEMBER 2020

Manufacturer:

Shenzhen Shiqiao Science and Technology Co.LTD

B2904, Nanshan Software Park, No.10128, Shennan Avenue, Liancheng Community, Nantou Street, Nanshan District, Shenzhen City

China

tel: +0086-755-26402003

Factory:

Shenzhen Shiqiao Science and Technology Co.LTD

B2904, Nanshan Software Park, No.10128, Shennan Avenue, Liancheng Community, Nantou Street, Nanshan District, Shenzhen City

China

tel: +0086-755-26402003

GLOVE DESCRIPTION

General glove description:

Disposable Nitrile Gloves

This glove is designed against 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	>	✓ Standard ✓ Instruction for use ✓ Marking			
§1.4	Manufacturer's instructions and information is available	V	Standard Instruction for use 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.	\	Standard Instruction for use Marking			
§2.5	PPE which may be caught up during use	V	Standard Instruction for use Marking			
§2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	V	✓ Standard ✓ Instruction for use ✓ Marking			

Glove constitution:

	Reference	Color	Material	Surfacic mass (g/m²)	Gauges	Thickness
Palm		Blue	Nitrile			0.05mm
Back		Blue	Nitrile			0.05mm
Cuff		Blue	Nitrile			0.05mm

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: 8/M-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)
8/M	190mm	168mm
9/L	210mm	175mm
10X/L	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.

Uncontrolled against viruses.

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S200807888_1 S200807891_1 (DMFU)	
EN ISO 374-5	S200807888_1	

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer:

Logo (€

Glove's reference: SQKC003

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:

100 pcs per box, 3000 pcs per carton

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:

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 sample and tested by a competent laboratory CTC Shanghai as per Air leak & Water leak testing once a year. 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

Shenzhen Shiqiao Science and Technology Co.LTD

B2904, Nanshan Software Park, No.10128, Shennan Avenue, Liancheng Community, Nantou Street, Nanshan District, Shenzhen City

China

Glove reference: SQKC003

Article code:

User notice index: 01

Last update: SEPTEMBER 2020



Glove description:

Disposable Nitrile Gloves

This 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: 8/M-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)
8/M	190mm	168mm
9/L	210mm	175mm
10X/L	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.

<u>Application</u> : Microorganism - EN ISO 374-5:2016







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 controlled, 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.

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.



Page 1/3

26 October 2020

3F, Building Block 2, No. 3400 Gonghexin Road, Jing'an District - Shanghai 200436, P.R. CHINA 上海市静安区共和新路3400号2幢3层

Tél.: +86 21 68 55 50 32 Fax: +86 21 68 55 50 33 E-mail: ctcshanghai@ctcgroupe.com

songjia@gts-lab.com

Report No.: S201010886_1

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY

CO., LTD (C41447)
B2904, NANSHAN SOFTWARE PARK, NO.

B2904, NANSHAN SOFTWARE PARK, NO.
10128, SHENNAN AVENUE, LIANCHENG
COMMUNITY, NANTOU STREET, NANSHAN DI

SHENZHEN GUANGDONG

CHINA

:23 Oct. 2020

Sample description: Disposable Nitrile Gloves

Style / Article no. :SQKC003

Test(s) requested :—
Service :REGULAR

Brand / Section :-Season :--

Buyer: --

End use :Disposable Nitrile Gloves

Factory name :-Factory code :--

For CE Marking : Yes

Previous report :-Product category :-Product type :--

Test stage :FIRST TEST

Supplier name :--Exported to :---

1. Conclusion:

	Tests description	<u>Conformity</u>
	EN ISO 21420	
1	Sizes and dimensions	None
	<u>Tests description</u>	<u>Conformity</u>
2	Phthalates	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

Approved by

Henry YAN
Laboratory Manager

Yvonne MAO

Senior Analytical Chemical Engineer



Page 2/3

Report No.: S201010886_1

26 October 2020

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY

CO., LTD (C41447)

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	<u>Description</u>	Sample information
	GLOVE		
		Whole glove	
		blue nitrile palm	



201010886



Page 3/3

Report No.: S201010886_1

26 October 2020

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY

CO., LTD (C41447)

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
5.1. Sizes and dimensions	EN ISO 21420: 2020				
Length of glove one-size			mm	243	
Length of glove one-size (2)			mm	242	
Length of glove one-size (3)			mm	245	

blue nitrile palm

	Method	Client Requirement	Unit	Result	Conformity
Phthalates	CEN ISO TS 16181 : 2011				Pass
BBP . Butyl benzyl phthalate		<1000	ppm	<25	
DBP . Di-butyl phthalate		<1000	ppm	<25	
DEHP . Di-(2-ethylhexyl) phthalate		<1000	ppm	<25	
DIBP . Di-isobutyl phthalate		<1000	ppm	<25	

END OF TEST REPORT







Page 1/5

10 August 2020

3F, Building Block 2, No. 3400 Gonghexin Road, Jing'an District - Shanghai 200436, P.R. CHINA 上海市静安区共和新路3400号2幢3层 Tél.: +86 21 68 55 50 32

Fax: +86 21 68 55 50 33
E-mail: ctcshanghai@ctcgroupe.com

Report No.: S200807888_1

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY

CO., LTD (C41447)

B2904, NANSHAN SOFTWARE PARK, NO. 10128, SHENNAN AVENUE, LIANCHENG COMMUNITY, NANTOU STREET, NANSHAN DI

SHENZHEN GUANGDONG

CHINA

Date of receipt :05 Aug. 2020 Testing period :05 Aug. 2020

:10 Aug. 2020

Buyer: --

Sample description: Disposable Nitrile Gloves

Style / Article no. :SQKC003

Test(s) requested :—
Service :REGULAR

Brand / Section :--

Season :--

End use :Disposable Nitrile Gloves

Factory name :—
Factory code :—

For CE Marking: Yes

Previous report

Product category

Product type :--

Test stage :FIRST TEST

Supplier name Exported to

1. Conclusion:

	<u>Tests description</u>	<u>Conformity</u>
	EN ISO 21420/EN ISO 374-1	
1	pH - Textile (KCl solution)	Pass
2	Aromatic amines derived from azo colorants	Pass
3	Polycyclic Aromatic Hydrocarbons (8)	Pass
4	Dexterity	Level 5
5	Air Leak Test	Pass
6	Water Leak Test	Pass
7	XRF screening	Pass
8	XRF screening (Tin)	Pass

	Tests description	<u>Conformity</u>
9	Phthalates	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable







Page 2/5

Report No.: S200807888_1

10 August 2020

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY

CO., LTD (C41447)

Approved by

Henry YAN

Laboratory Manager

Yvonne MAO

Senior Analytical Chemical Engineer







Page 3/5

Report No.: S200807888_1

10 August 2020

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY

CO., LTD (C41447)

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	<u>Description</u>	Sample information
	GLOVE		
		Whole glove	
		blue nitrile palm	



200807888







Page 4/5

Report No.: S200807888_1

10 August 2020

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY

CO., LTD (C41447)

3. GLOVE/

Whole glove

	Method	Client	Unit	Result	Conformity
		Requirement			
5.2. Dexterity	EN ISO 21420: 2020				
Smallest diameter of pin fulfilling test condition			mm	5.0	
Smallest diameter of pin fulfilling test condition (2)			mm	5.0	
Smallest diameter of pin fulfilling test condition (3)			mm	5.0	
Smallest diameter of pin fulfilling test condition (4)			mm	5.0	
Performance level				5	
▲ Air Leak Test	EN 374-2:2019				Pass
Glove thickness			mm	0.05	
Air pressure used to test			kPa	2.5	
Result		No air bubbles		No air bubbles	
▲ Water Leak Test	EN 374-2:2019				Pass
Result		No water leak		No water leak	

blue nitrile palm

	Method	Client Requirement	Unit	Result	Conformity
(+) 4.2. pH - Textile (KCI solution)	ISO 3071:2020				Pass
pH value		3.5< - <9.5		8.3	
4.2. Aromatic amines derived from azo colorants	ISO 14362-1:2017 (w/o extraction)				Pass
Accessible without fibre extraction		<30	mg/kg	<5	
▲ 4.2. Polycyclic Aromatic Hydrocarbons (8)	ISO/TS 16190: 2013				Pass
Benzo(a)anthracene		<1	mg/kg	<0.1	
Chrysene		<1	mg/kg	<0.1	
Benzo(b)fluoranthene		<1	mg/kg	<0.1	
Benzo(k)fluoranthene		<1	mg/kg	<0.1	
Benzo(a)pyrene		<1	mg/kg	<0.1	
Dibenzo(a.h)anthracene		<1	mg/kg	<0.1	

The report is issued by CTC Shanghai under its General Conditions printed overleaf. The results shown in this report refer only to the sample by test Except by special arrangement, the test items will not be retained by CTC Shanghai for more than 3 months. The test report shall not be reproduced, except in full, without the written approval of the testing laboratory.







Page 5/5

Report No.: S200807888_1

10 August 2020

APPLICANT: SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY CO., LTD (C41447)

	00., 212 (01111.)					
	Method	Client	Unit	Result	Conformity	
		Requirement				
Benzo(e)pyrene		<1	mg/kg	<0.1		
Benzo(j)fluoranthene		<1	mg/kg	<0.1		
Phthalates	CEN ISO TS 16181 : 2011				Pass	
BBP . Butyl benzyl phthalate		<1000	ppm	<25		
DBP . Di-butyl phthalate		<1000	ppm	<25		
DEHP . Di-(2-ethylhexyl) phthalate		<1000	ppm	<25		
DIBP . Di-isobutyl phthalate		<1000	ppm	<25		
(+) XRF screening	ASTM F2617 - 15				Pass	
Cd (Cadmium)		<100	ppm	<100		
XRF screening (Tin)	ASTM F2617 - 15				Pass	
Sn (Tin)		<150	ppm	<150		

END OF TEST REPORT

(+)CNAS accreditation

A: The test was carried out by external accredited laboratory under their accreditation scope.

Table of Performance Level for Glove

Test Item	Performance Level						
Tool Hom	0##	1	2	3	4	5	
Finger dexterity (EN ISO 21420) Smallest diameter of pin fulfilling test conditions (mm)		11.0	9.5	8.0	6.5	5.0	

Performance level 0 means the glove falls below the minimum performance level for the given individual hazard