



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° 0075/1445/162/04/21/0718 EXT 01/08/22

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

Manufacturer : **KCL GmbH**
Am Kreuzacker 9 36124 Eichenzell
Germany

Description

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

Product reference : **SivoChem® 759**

Glove description : **Chemical protective nitrile glove, powderfree**

Available sizes : **7, 8, 9, 10, 11**

Pictures :



Label for the polybag	
CE 0197	Art. 759 size 09
YYYY-MM	SivoChem® 759
	20 pairs
KCL-Code:	EAN-Code BAR-Code
EN ISO 374-1 Type B KPT	EN ISO 374-5 Virus
KCL GmbH	Am Kreuzacker 9 D-36124 Eichenzell www.kcl.de

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 AND VIRUS

EN ISO 374-1:2016 + A1:2018

**Type B
KPT**

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 D (Tüv Rheinland LGA Products 0197)

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 index 01 dated from August 2022 and the Instruction for Use UI 759 v01.

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
Nadine PIPAZ
CE Expert Team Coordinator

Date of first issue : 05 August 2022
End of validity date : 05 August 2027



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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



KCL GmbH

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

Reference of the product	:	SivoChem® 759
Article code	:	/
Technical file index	:	01
Last update	:	August 2022

IDENTIFICATION

Reference of the product :	:	SivoChem® 759
Article code :	:	/
Minor Variant	:	Flextril™ 729
Technical file index :	:	01
Last update :	:	August 2022

Manufacturer :

KCL GmbH

Am Kreuzacker 9 36124 Eichenzell

Germany

tel : +49 (0) 6659 87 211

fax : N/A

Factory :

KCL GmbH

Am Kreuzacker 9 36124 Eichenzell

Germany

tel: +49(0)6659 87 211

fax: N/A

GLOVE DESCRIPTION

General glove description and intended use:

Chemical protective nitrile glove, powderfree

This glove is designed against chemical risks , against microorganisms and virus 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 checked="" 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 ²)	Gauges	Thickness
Palm	3000046	blue	Nitril rubber			0,18 mm +/- 3 mm
Back	3000046	blue	Nitril rubber			0,18 mm +/- 3 mm
Cuff	3000046	blue	Nitril rubber			0,18 mm +/- 3 mm

PROTECTION SCOPE

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

This glove is designed against chemical risks , against microorganisms and virus risks.

It is a category III product, module D

Notified Body Reference : Tüv Rheinland LGA Products (0197)
Tillystrasse 2 90431 Nürnberg GERMANY

GENERAL REQUIREMENTS

Standard EN ISO 21420 : 2020

Dexterity : 5

Available size range: 7, 8, 9, 10, 11

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	186-190	183-185
8	210-214	192-194
9	224-228	206-209
10	248-252	200-202
11	272-276	217-219

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

Type :	Type B
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Tested chemical :	CAS N°	Letter	Permeation performance levels:	Degradation value:
Sodium hydroxide 40%	1310-73-2	K	6	5,3%
Hydrogen peroxide 30%	7722-84-1	P	4	64,7%
Formaldehyde 37%	50-00-0	T	6	35,2%

Microorganism EN ISO 374-5 : 2016

This glove protect against microorganism.

Controlled against viruses.

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	L200711806_1 CHM0329637/2214/JH/A	
EN 374-2	L200711805_1	
EN 16523-1	CHM0329637/2214/JH/B CHM0329637/2214/JH/C	
EN ISO 374-5		20.01880.02 (Centexbel)
Other		55575 U 21 (Isega)

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo **CE**

Glove's reference : SivoChem® 759

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 :



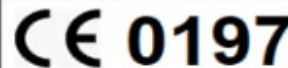





Date of obsolescence (month/year) if applicable:

Marking example :

Label for the polybag	
0197	Art. 759 size 09
YYYY-MM	SivoChem® 759
	20 pairs
KCL-Code:	EAN-Code BAR-Code
EN ISO 374-1 Type B KPT EN ISO 374-5 Virus	
KCL GmbH Am Kreuzacker 9 D-36124 Eichenzell www.kcl.de	

Marking of packaging example :

Label for the carton

 Honeywell  Pat.: hsmrats.com	 0197   YYYY-MM  KCL-Code:  EN ISO 374-1 Type B KPT  EN ISO 374-5 Virus	Art. 759 size 09
		SivoChem®759
		<i>KCL-Code as Barcode, Type 128 Charset A</i>
		200 Pairs
		<i>EAN-Code BAR-Code</i>
	KCL GmbH Am Kreuzacker 9 D-36124 Eichnezell www.kcl.de	

Method of marking on the glove :

label on polybag

Packaging suitable for transport:

200 pairs per carton / 20 pairs of gloves in a single polybag.

PPE subject to ageing :

Peremption period : 60 months / 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, ...).

Cleaning instructions:

The gloves are not washable.

MEANS OF CONTROL

Final inspection plan: in accordance to DIN ISO 2859-1:2014-08

Sampling plan for reduced inspection / special inspection level S-3

Quantity of acceptable defects: Major defects → Ac 0 / Re 1

Test methods: visual inspection; EN ISO 21420, EN 16523-1, EN 374,