



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

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 , microorganisms risks*

Product reference : Flextril™ 729

Article code : /

Glove description : Chemical protective nitrile glove, powderfree

Available sizes : 7 8 9 10

Pictures :



	CE 0197		Art. 729 size 09
			Flextril™ 729
		KCL-Code: <small>EN ISO 374-1 Typ B JKPT</small>	<small>KCL-Code as Barcode, Type 128 Charset A</small>
			<small>EN ISO 374-5 Virus</small>
<small>KCL GmbH</small>		<small>D-36124 Eichenzell</small>	<small>www.kcl.de</small>

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
TPKJ**

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 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
Didier GUISSADO
Certification and Quality Manager

Date of first issue : 19 April 2021
End of validity date : 19 April 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:
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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	:	Flextril™ 729
Article code	:	/
Technical file index	:	01
Last update	:	April 2021

IDENTIFICATION

Reference of the product : : Flextril™ 729
Article code : : /
Basic Model
Technical file index : : 01
Last update : : April 2021

Manufacturer :

KCL GmbH

Am Kreuzacker 9 36124 Eichenzell

Germany

tel : +49 (0) 6659 87 211

fax :

Factory :

KCL GmbH

Am Kreuzacker 9 36124 Eichenzell

Germany

tel: +49(0)6659 87 211

fax:

GLOVE DESCRIPTION

General glove description and intended use:

Chemical protective nitrile glove, powderfree
 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
§2.2	PPE is designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input 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			0,2 mm
Back	3000046	Blue	Nitril rubber			0,2 mm
Cuff	3000046	Blue	Nitril rubber			0,2mm

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 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

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	182 - 186	277
8	208 - 214	278
9	236 -240	280
10	258-262	286

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

Tested chemical :	CAS N°	Letter	Permeation performance levels:	Degradation value:
Formaldehyde 37%	50-00-0	T	6	18,0%
Hydrogen peroxide 30%	7722-84-1	P	4	31,0%
Sodium hydroxide 40%	1310-73-2	K	6	-15,0%
n-Heptane	142-82-5	J	3	31,0%

Microorganism EN ISO 374-5 : 2016

This glove protect against microorganism.
Controlled against viruses.


TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	L200711805_1; L200711806_1	
EN 374-2	L200711805_1	
EN 16523-1	L200711807_1	
EN ISO 374-5		20.01880.02 (Centexbel)
Other		392-2021-00122301_XV_EN (Eurofins)

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : Flextril™ 729

Article Code : /

Size indicator

Pictograms related to risks against which protection is offered with performance levels

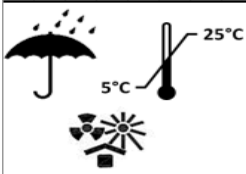





Information pictogram

Address of Manufacturer :

Date of Manufacture (month/year) and/or serial/batch number :

Date of obsolescence (month/year) if applicable:

Marking example :

	CE 0197  YYYY-MM 	Art. 729 size 09
		Flextril™ 729 KCL-Code as Barcode, Type 128 Charset A
Honeywell 	KCL-Code:  EN ISO 374-1 Typ B JKPT	100 pairs
	 EN ISO 374-5 Virus	EAN-Code BAR-Code
KCL GmbH		D-36124 Eichenzell
www.kcl.de		

Marking of packaging example :



Method of marking on the glove :

Marking of the box/carton

Packaging suitable for transport:

100 pairs per box/carton

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 420, EN ISO 21420, EN 16523-1, EN 374,