

# **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° 0075/3074/162/01/19/0366

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

Manufacturer :	Supermax Healthcare Limited Units 12-16 Titan Drive, Peterborough, PE1 5XN, UK
	UK
Description	
PPE Type :	protective glove against mechanical risks, chemical risks, microorganisms risks
Product reference :	CHEM-MAX
Article codes :	301-7, 301-8, 301-9, 301-10
Glove description :	Nitrile Unsupported, Flock, Open Cuff
Available sizes :	7/S(CHEM-MAX 301-7) 8/M(CHEM-MAX 301-8) 9/L(CHEM-MAX 301-9) 10/XL(CHEM-MAX 301-10)
Pictures :	

Pictur



CHEM-MAX	CHEM-MAX
*7 Size S	Size 8 Size M
AURELIA	AURELIA® CHEM-MAX
109 Sue L	Star 10 Star XL

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

Reference standard :

EN 420:2003+A1:2009			
EN 388:2016	3 1 0 1 X « X »indicates that the glove has not been submitted to the test or the te method appears not to be suitable for the glove design or material.		
EN ISO 374-5:2016	MICRO-ORGANISMS		
EN ISO 374-1:2016	Туре В		
	JKL		
This product is a category III (letal or irreversible risk). This cert according to module C2 (CTC 0075)	tificate shall only be used in conjuncture with the conformity assessment procedure		
At the date of certificate the product is in compliance with Ann	nex XVII of REACh regulation (n° 1907/2006 and revisions)		
Full description of the PPE, reference rules verified in the contex manufacturer's technical file index 01 dated from February 2019	tt of the EU-type examination and information given on the product are detailed in the		
	ent object of this EU type approval certificate or any modification of the information contained in the pe approval certificate (change of address, change of company status) should be brought to the attentic 425.		
Issued in Lyon by	Date of first issue : 04 February 2019		
Maxence DREVET	End of validity date : 05 July 2023		
Project Certification Manager	www.ctcgroupe.com		
In application of the Regulation 2016/425 of the European parliament and the Council of 9th March 2016 related	cemarking@ctcgroupe.com		
to Personal Protective Equipment and repealing the Directive 89/686/EEC.	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		

**Supermax Healthcare Limited** 

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

Reference of the product	:	CHEM-MAX
Article code	:	301-7, 301-8, 301-9, 301-10
Technical file index	:	01
Last update	:	February 2019



C0366 - SUPERMAX HEALTHCARE LIMITED - N°0075-3074-162-01-19-0366 - Dossier technique

# IDENTIFICATION

Reference of the product : Article code : Basic Model Technical file index : Last update : CHEM-MAX 301-7, 301-8, 301-9, 301-10 01 February 2019

### Manufacturer :

Supermax Healthcare Limited Units 12-16 Titan Drive,Peterborough,PE1 5XN,UK UK tel: 01733 615215

fax : 01733 615205

#### Factory :

NANTONG QIANGSHENG SAFETY PROTECTION TECHNOLOGY No.118, JIALINGJIANG ROAD, RUDONG ECONOMIC DEVELOPMENT ZONE, JIANGSU PROVINCE, P.R. CHINA

#### CHINA

- tel: 86-513-4108356
- fax: 86-513-4108190

NANTONG QIANGSHENG SAFETY PROTECTION TECHNOLOGY CO, LTD. YOUYI ROAD (W), JUEGANG, RUDONG JIANGSU

# CHINA

tel: 86-513-4108356

fax: 86-513-4108190

NANTONG QIANGSHENG SAFETY PROTECTION TECHNOLOGY CO, LTD. JINSHAJIANG ROAD, NEW INDUSTRIAL ZONE, RUDONG, JIANGSU

#### CHINA

tel: 86-513-84129800

fax: 86-513-84129808

NANTONG QIANGSHENG SAFETY PROTECTION TECHNOLOGY CO, LTD. JINSHAJIANG ROAD, JUEGANG, RUDONG JIANGSU CHINA

tel: 86-513-84129800

fax: 86-513-84129808

# **GLOVE DESCRIPTION**

#### General glove description :

Nitrile Unsupported, Flock, Open Cuff

type of coating finish : smooth

Visual description (picture back and palm sides) :



#### Field of use

Effective barrier against bacteria and fungi, but "Uncontrolled against viruses" and having a protection against tested chemicals n-heptane, NaOH40%, H2SO4 96% conditions.

	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	7	Standard Instruction for use Marking		
§2.5	PPE which may be caught up during use	$\checkmark$	Standard  Instruction for use Marking		
§2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	~	✓     Standard       ✓     Instruction for use       ✓     Marking		
§2.14	Multi-risk PPE	<b>V</b>	<ul> <li>✓ Standard</li> <li>✓ Instruction for use</li> <li>✓ Marking</li> </ul>		
§3.3	The PPE is intended to protect against mechanical injuries	7	<ul> <li>✓ Standard</li> <li>✓ Instruction for use</li> <li>✓ Marking</li> </ul>		
§3.10.2	PPE intended to protect against substances and mixtures which are hazardous to health and against harmful biological agents - Cutaneous contact	~	✓     Standard       ✓     Instruction for use       ✓     Marking		

#### Available sizes :

Minimum length of glove (mm)	Sizes
330(palm width:101)	7/S(CHEM-MAX 301-7)
330(palm width:113)	8/M(CHEM-MAX 301-8)
330(palm width:125)	9/L(CHEM-MAX 301-9)
330(palm width:130)	10/XL(CHEM-MAX 301-10)

#### **Glove constitution :**

	Reference	Color	Material	Surfacic mass	Gauges	Thickness
Palm		Green	Nitrile	150g/m2		0.51-0.57mm
Back		Green	Nitrile	150g/m2		0.51-0.57mm
Cuff		Green	Nitrile	150g/m2		0.51-0.57mm

# **PROTECTION SCOPE**

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

This glove is designed for mechanical risks, chemical risks, microorganisms risks.

It is a category III product, module C2

Notified Body Reference : CTC (0075)

4, rue Hermann Frenkel - 69367 Lyon cedex 07 - France

#### **GENERAL REQUIREMENTS**

#### Standard EN 420 : 2003 + A1 : 2009

5

Dexterity :

Size : conform

At the date of certificate the product is in compliance with Annex XVII of REACh regulation (n° 1907/2006 and revisions)

### SPECIFIC REQUIREMENTS AND PERFORMANCE LEVELS

### Mechanical hazard EN 388 : 2016

Protection offered	Performance levels
Abrasion resistance	3
Blade cut resistance	1
Tear strength resistance	0
Puncture resistance	1
Cut Resistance method (EN ISO 13997)	X
Impact Protection	-

The levels of performance have been measured on the palm

« 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.

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

Protection offered	Performance levels
Water tighness	conform
Air tighness	conform

# Chemical hazard EN ISO 374-1 : 2016

Type : Type B

Tested chemical :	CAS N°	Letter	Permeation performance levels:	Degradation value:
n-Heptane	142-82-5	J	6	14,50%
Sodium hydroxide 40%	1310-73-2	K	6	1,90%
Sulphuric acid 96%	7664-93-9	L	3	69,70%

#### Microorganism EN ISO 374-5 : 2016

This glove protect against microorganism Uncontrolled against viruses

# TEST REPORTS

Laboratory	CTC	Other
EN 420 + innocuousness	S180100135_2 (DMFU) H161205025_1(PAHs) S160807620_1(tin, cad) 07582-14 S180506405_2	
EN 388	H161204632_1 07586-14 07585-14	
EN 374-2	S171216312_1	
EN 16523-1	S171216312_1	

# MARKING - PACKAGING

#### Information printed on the glove :

Logo of Manufacturer : Logo C C Followed by the number of notified body in charge of control of the production (0075) Glove's reference : CHEM-MAX Article Code : 301-7, 301-8, 301-9, 301-10 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 number :