



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° 0075/4472/162/12/21/2127

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

Manufacturer : Shanghai Shengda Medical Applications Co., Ltd.
No. 608, Xingwen Rd., Jiading, Shanghai
China

Description

PPE Type : *protective glove against chemical risks*

Product reference : SD-PE-001

Glove description : Polyethylene Glove (PE glove)

Available sizes : 13

Pictures :



Polyethylene Glove (PE)
Art. No. SD-PE-001
Size 13
CAT III

CE 0075

EN ISO 374-1:2016/A1:2018/Type C

Manufacturer: Shanghai Shengda Medical Applications Co., Ltd.
Address: No. 608, Xingwen Rd., Jiading, Shanghai, China
Importer: Intervet Productions S.A.
Address: Rue de Lyons 27460 IGOVILLE France

Production Date : MM/YYYY
Use by Date : MM/YYYY
Instructions & Declaration:
[http:// www.sh-shengda.com/instructions/](http://www.sh-shengda.com/instructions/)

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 374-1:2016 / A1:2018

Type C

KT

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 C2 (CTC 0075)

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 December 2021 and the Instruction for Use V01 2021/11/29.

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 Manager

Date of first issue : 13 December 2021
End of validity date : 13 December 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

Shanghai Shengda Medical Applications Co., Ltd.

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

Reference of the product	:	SD-PE-001
Article code	:	/
Technical file index	:	01
Last update	:	December 2021

IDENTIFICATION

Reference of the product :	:	SD-PE-001
Article code :	:	/
Basic Model		
Technical file index :	:	01
Last update :	:	December 2021

Manufacturer :

Shanghai Shengda Medical Applications Co., Ltd.

No. 608, Xingwen Rd., Jiading, Shanghai

China

tel : 86-21-33517332

fax : 86-21-33517337

Factory :

Shanghai Shengda Medical Applications Co., Ltd.

No. 608, Xingwen Rd., Jiading, Shanghai

China

tel: 86-21-33517332

fax: 86-21-33517337

GLOVE DESCRIPTION

General glove description and intended use:

Polyethylene Glove (PE glove)

This glove is designed against chemical 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
§2.4	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 ²)	Gauges	Thickness
Palm		transparent	PE (Polyethylene)			0.010-0.022mm
Back		transparent	PE (Polyethylene)			0.010-0.022mm
Cuff		transparent	PE (Polyethylene)			0.010-0.022mm

PROTECTION SCOPE

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

This glove is designed against chemical 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 ISO 21420 : 2020

Dexterity : level 5

Available size 13
 range:

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)
13	340±5	290±5

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 :	Sodium hydroxide 40%
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Tested chemical :	CAS N°	Letter	Permeation performance levels:	Degradation value:
Sodium hydroxide 40%	1310-73-2	K	6	5,3%
Formaldehyde 37%	50-00-0	T	6	11,2%


TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S210808223_2	
EN 374-2	S210808223_2	
EN 16523-1	S210808223_2	
Other	S210808223_2(EN 374-4)	

MARKING - PACKAGING

Information printed on the glove :

Logo of Manufacturer :

Logo 

Glove's reference : SD-PE-001

Article Code : /

Size indicator

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

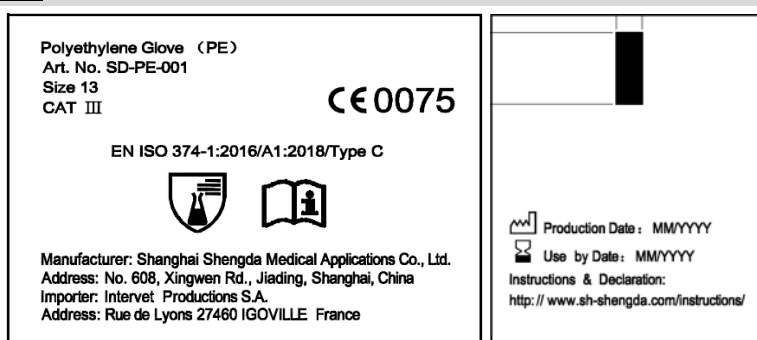
Information pictogram

Address of Manufacturer :

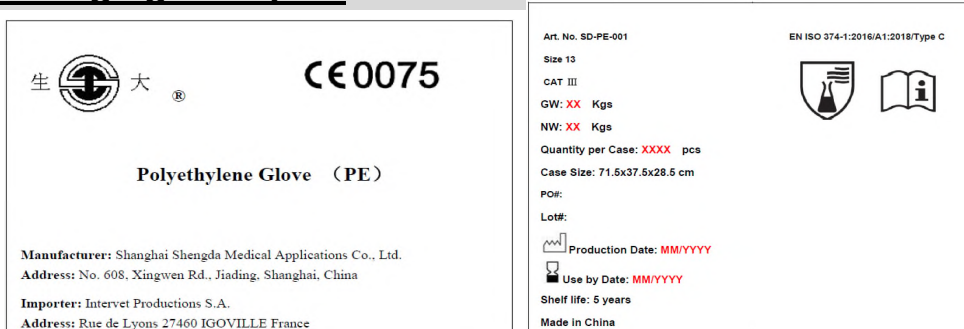
Date of Manufacture (month/year) and/or serial/batch number :

Date of obsolescence (month/year) if applicable:

Marking example :



Marking of packaging example :



Method of marking on the glove :

print on the polybag and carton

Packaging suitable for transport:

1 pair / polybag, 340 pairs / paper box, 8160 pairs / carton

PPE subject to ageing :

Peremption period : 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

- 1、 IQC: We inspect every batch of the raw material according to the sampling inspection plan specified in the SOP before we accept them from our supplier, and keep them at proper place and condition.
- 2、 IPQC: We do the IPQC according to the sampling inspection plan specified in the SOP, including appearance, size, weight and water-tightness.
- 3、 OQC: We do the OQC according to the sampling inspection plan specified in the SOP, including appearance, size, weight, water-tightness and decoration resistance. We inspect sample and perform water leak based on ISO 9001 once a year.

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CQM has issued an IQNet recognized certificate that the organization:

Shanghai Shengda Medical Applications Co., Ltd.

for the following scope:

Production of ultra-thin precision lenses (flat lens), production and packing of handressing plastic gloves products

For the each site and certification scope to the attachment has implemented and maintains a Quality Management System

which fulfills the requirements of the following standard:

ISO 9001:2015

*Issued on: 2019-09-29
Expires on: 2022-09-28*

* This attention is directly linked to the IQNet Partner's original certificate and shall not be used as a stand alone document

Registration Number: CN-00219Q25343R0M

Alex Stoichiloiu
President of IQNet

Ji XiaoDong
General Manager of CQM

IQNet Partners*
AENOR Spain AFNOR Certification France AFNOR Portugal CCC Cqirus CSQ Italy CQC China CQM China CQS Czech Republic Cas Cert Croatia DQS Hamburg GmbH Germany PCAY Brazil FORDOR/DMA Universidade ICFE/CB Colombia Inspira Serbitissimi Oy Finland INTECO Costa Rica ISM Argentina JQA Japan KPO Korea MBTEC Greece MS&T Hungary Nemko AS Norway NSI Ireland NYCE/SIDE Mexico PCHC Poland Quality Austria Austria S&S Russia SH Jansel IQD Slovenia SERIM QAS International Malaysia RQS Switzerland SRAC Romania TSEI Sp Petersburg (Russia) TSE Turkey YUQS Serbia IQNet is represented in the USA by: AFNOR Certification, CQI, DQS Holding GmbH and RAI Inc.

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IQNet
THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CQM has issued an IQNet recognized certificate that the organization:

Annex (1) to IQNet Certificate Number CN-00219Q25343R0M

Organization	Certification Address(Post Code)	This certificate is valid to the following product(s)/service
Shanghai Shenda Medical Applications Co., Ltd.	No.608, Xingwen Rd., Jindong District, Shanghai, P.R.China(201815)	Production of ultra-thin precision lenses (flat lens), production and packing of handressing plastic gloves products
Shanghai Shenda Medical Applications Co., Ltd.	No.4625, Shuangzhu Rd., Jindong District, Shanghai, P.R.China(201815)	Production and packing of handressing plastic gloves products
WEALTH ON (Jiangsu) Co., Ltd.	Dongyuan Village, Hengji Town, Jianhu County, Yancheng City, Jiangsu, P.R.China(224763)	Production packing of handressing plastic gloves products

*Issued on: 2019-09-29
Expires on: 2022-09-28*

(This annex is effective only using with home page)

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Alex Stoichiloiu
President of IQNet

Ji XiaoDong
General Manager of CQM

IQNet Partners*
AENOR Spain AFNOR Certification France AFNOR Portugal CCC Cqirus CSQ Italy CQC China CQM China CQS Czech Republic Cas Cert Croatia DQS Hamburg GmbH Germany PCAY Brazil FORDOR/DMA Universidade ICFE/CB Colombia Inspira Serbitissimi Oy Finland INTECO Costa Rica ISM Argentina JQA Japan KPO Korea MBTEC Greece MS&T Hungary Nemko AS Norway NSI Ireland NYCE/SIDE Mexico PCHC Poland Quality Austria Austria S&S Russia SH Jansel IQD Slovenia SERIM QAS International Malaysia RQS Switzerland SRAC Romania TSEI Sp Petersburg (Russia) TSE Turkey YUQS Serbia IQNet is represented in the USA by: AFNOR Certification, CQI, DQS Holding GmbH and RAI Inc.

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