CE Technical Construction File (TCF)

Document No. : JS31015

According to the EC Medical Device Directive

(93/42/EEC)

Related to the
Disposable Vinyl (Synthetic) Examination Gloves

Version: A/1

Date：08-Oct-2016

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1.1， Manufacturer Information

Company name: ***Jiangsu Jaysun Glove Co., Ltd***

Company Logo:

Company Address: No.199 Jianling Rd, Economic Developing-area, Suqian City, Jiangsu, China

Post Code: 223800

Tel: 86-527-88319930

Fax: 86-527-88319289

1.2, Brief Introduction

JIANGSU JAYSUN GLOVE CO., LTD is located in Suqian City, Jiangsu Province, having an area of sixty-five acreage. It is a specialized manufacturer of vinyl (PVC) and synthetic examination gloves. With 24 advanced production lines to founded, the annual output volume will exceed 2,800,000,000 pcs gloves.

Choosing the best imported raw materials, with stable and reliable quality, our products are being exported to the USA, Canada, Europe and Australia, with clients in more than 20 countries and districts overall.

Our gloves have advantages in resistant to acid, alkali, dirt and germs. Besides, they can be worm on either hand, and are easy to put on and take off. Suitable for use in numerous applications, our various terms are widely used in food, chemical, electronic，pharmacy, painting and coating, printing and dyeing, agricultural and other industries.

Based on honesty and sincerity, we have earned a high reputation around the world. We sincerely welcome all customers to cooperate with us, and we guarantee the best products and service.

1.3, Product Introduction

Characteristics of Disposable Vinyl (Synthetic) Examination Gloves:

The materials of disposable vinyl (synthetic) examination gloves are almost the same as common vinyl gloves except that there is a special agent enhanced the flexibility of the gloves. Though they look like latex gloves from the appearance, they are made by synthetic materials, 100% latex free, and have no allergic reaction to human body skin. The physical capability is better than that of common vinyl gloves.

Use of the Gloves:

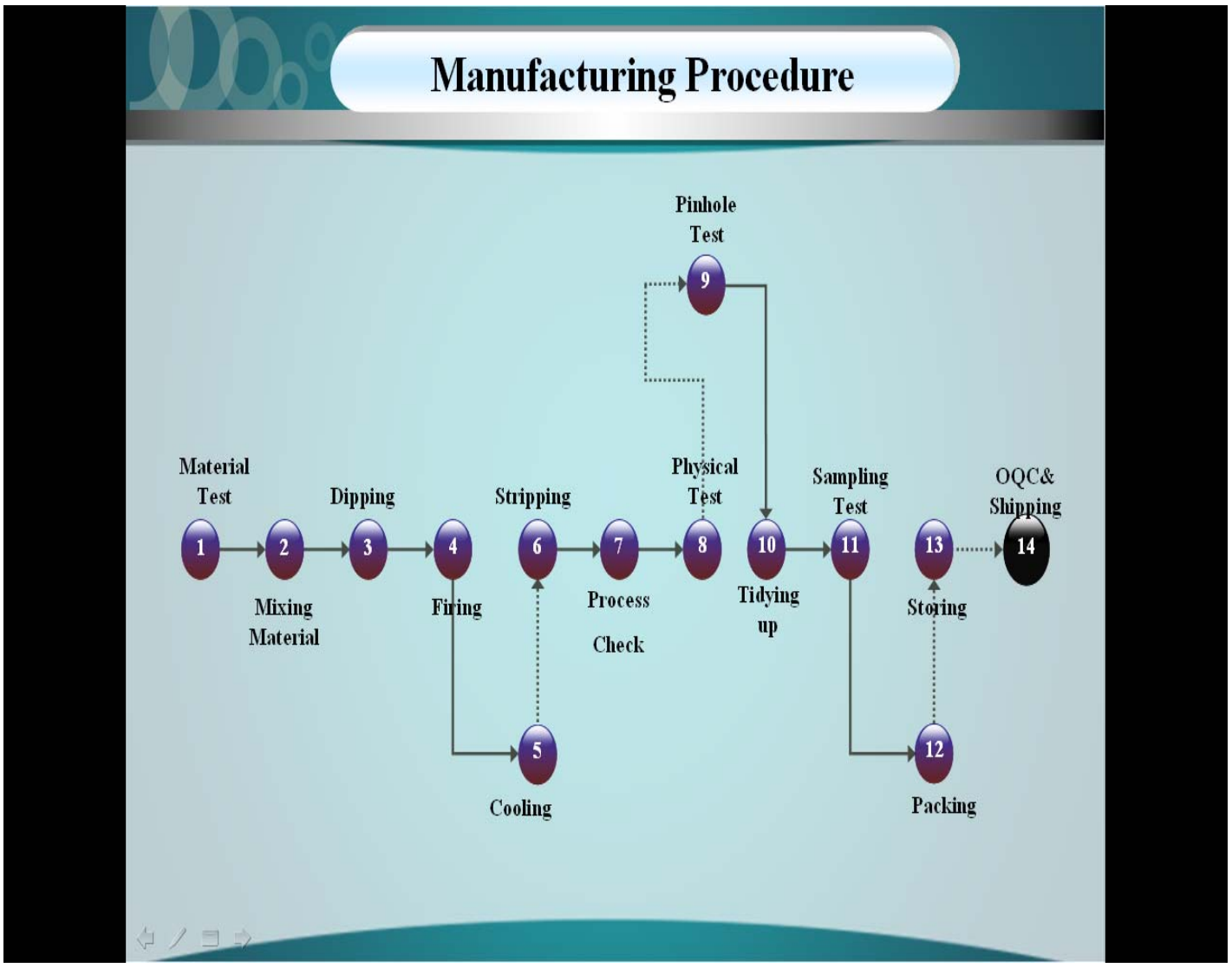
Widely used in Medical Examination, hygiene inspection, chemical industry and pharmacy. These products provide users with protection when working in these areas.

1.4, Products diagram and specification

1.4.1, Product Diagram:

The below diagram have described the manufacturing procedures of Disposable gloves of Jaysun Glove

The Manufacturing process is as below：
Material test-→Mixing material-→Dipping-→Firing→Cooling-→Stripping-→ Process Check-→Physical Test-→Pinhole Test-→Tiding up-→Sampling Test →Packing-→Storing-→OQC & Shipping



1.4.2, Product items and specification.

We only produce vinyl examination gloves, but they are in different weight:

Products No.	Item No.	Description	XS（0）	S（1）	M（2）	L（3）	XL（4）
1	JP-102/ JP-112	Powdered/Powder-free	4.0±0.3g	5.0±0.3g	5.5±0.3g	6.0±0.3g	6.2±0.3g
2	202/212	Powdered/Powder-free	4.0±0.3g	4.5±0.3g	5.0±0.3g	5.5±0.3g	5.7±0.3g
3	402/412	Powdered/Powder-free	4.0±0.3g	4.0±0.3g	4.5±0.3g	5.0±0.3g	5.3±0.3g
4	602/612	Powdered/Powder-free	-	3.5±0.3g	4.0±0.3g	4.5±0.3g	4.7±0.3g

1.4.2.1 Specification of JP-102 /JP- 112 items:

Size:	Length (mm)	Palm width (mm)	Cuff thickness (Min: mm)	Palm thickness (Min: mm)	Finger thickness (Min: mm)	Cuff rolling （mm）
S	≥230 (for US and Japan market.). ≥230 (for Europe market.)	85±3	0.05	0.08	0.05	1.2±0.2
M		95±3				1.2±0.2
L		105±3				1.2±0.2
XL		115±3				1.2±0.2
Elongation rate	≥11 Mpa	Tensile Strength		≥300%		
Force at break	≥ 3.6N (for European market 3mm dumb-bell cutting) ≥ 7.0N (for Non-European market, 6mm dumb-bell cutting)	Water leak AQL Level		AQL1.5~AQL2.5 as per customer requirements		
Special quality will be follow as per customers' special requirement.						

1.4.2.2 Specification of 202 / 212 items:

Size:	Length (mm)	Palm width (mm)	Cuff thickness	Palm thickness	Finger thickness	Cuff rolling （mm）

			(Min: mm)	(Min: mm)	(Min: mm)	
S	≥230 (for US and Japan market.). ≥230 (for Europe market.)	85±3	0.05	0.07	0.05	1.2±0.2
M		95±3				1.2±0.2
L		105±3				1.2±0.2
XL		115±3				1.2±0.2
Elongation rate	≥11 Mpa	Tensile Strength		≥300%		
Force at break	≥ 3.6N (for European market 3mm dumb-bell cutting) ≥ 7.0N (for Non-European market, 6mm dumb-bell cutting)	Water leak AQL Level		AQL1.5~AQL2.5 as per customer requirements		
Special quality will be follow as per customers' special requirement.						

1.4.2.3 Specification of 402 / 412 items:

Size:	Length (mm)	Palm width (mm)	Cuff thickness (Min: mm)	Palm thickness (Min: mm)	Finger thickness (Min: mm)	Cuff rolling （mm）
S	≥230 (for US and Japan market.). ≥230 (for Europe market.)	85±3	0.045	0.06	0.05	1.2±0.2
M		95±3				1.2±0.2
L		105±3				1.2±0.2
XL		115±3				1.2±0.2
Elongation rate	≥11 Mpa	Tensile Strength		≥300%		
Force at break	≥ 3.0N (for European market 3mm dumb-bell cutting) ≥ 6.0N (for Non-European market, 6mm dumb-bell cutting)	Water leak AQL Level		AQL2.5~AQL4.0 as per customer requirements		
Special quality will be follow as per customers' special requirement.						

1.4.2.4 Specification of 602 / 612 items:

Size:	Length (mm)	Palm width (mm)	Cuff thickness (Min: mm)	Palm thickness (Min: mm)	Finger thickness (Min: mm)	Cuff rolling （mm）
S	≥230 (for US and Japan market.). ≥230 (for Europe market.)	85±3	0.04	0.06	0.05	1.2±0.2
M		95±3				1.2±0.2
L		105±3				1.2±0.2
XL		115±3				1.2±0.2
Elongation rate	≥9 Mpa	Tensile Strength		≥280%		
Force at break	≥ 2.5N (for European market 3mm dumb-bell cutting) ≥ 5.0N (for Non-European market, 6mm dumb-bell cutting)	Water leak AQL Level		AQL 4.0		
Special quality will be follow as per customers' special requirement.						

1.4.3. Product pictures

1.5. Quality Management System:

ISO13485, ISO9001, ISO14001:

Certificate of Registration

nqa

This is to certify that the Quality Management System of

Jiangsu Jaysun Glove Co., Ltd.

Organization Code : 91321300779665160F

Operation Address : No.199, Jianling Rd., Suqian Economic Developing-Area,Jiangsu Province, China

Registered Address : No.199, Jianling Rd., Suqian Economic Developing-Area,Jiangsu Province, China

applicable to

Production and Sales of Disposable Non-sterile Vinyl(Synthetic) Examination Gloves

has been assessed and registered by NQA against the provisions of

ISO 13485: 2003

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

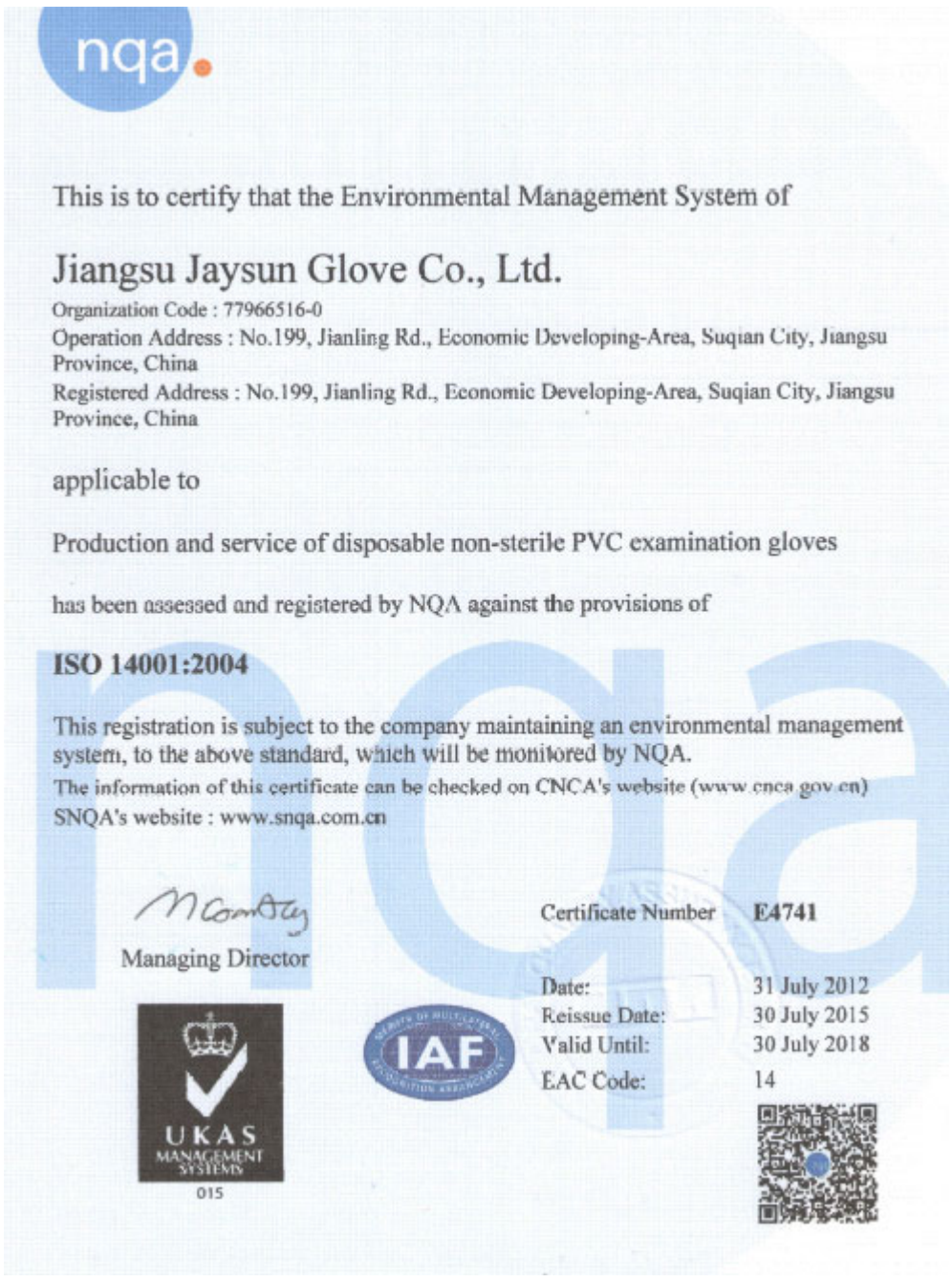
The information of this certificate can be checked on CNCA's website (www.cnca.gov.en)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number **23182**

Date: 18 May 2007
Reissue Date: 17 May 2016
Valid Until: 31 March 2019
EAC Code: 14

UKAS MANAGEMENT SYSTEMS 015



nqa.

This is to certify that the Environmental Management System of

Jiangsu Jaysun Glove Co., Ltd.

Organization Code : 77966516-0
Operation Address : No.199, Jianling Rd., Economic Developing-Area, Suqian City, Jiangsu Province, China
Registered Address : No.199, Jianling Rd., Economic Developing-Area, Suqian City, Jiangsu Province, China

applicable to

Production and service of disposable non-sterile PVC examination gloves

has been assessed and registered by NQA against the provisions of

ISO 14001:2004

This registration is subject to the company maintaining an environmental management system, to the above standard, which will be monitored by NQA.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number E4741

Date: 31 July 2012
Reissue Date: 30 July 2015
Valid Until: 30 July 2018
EAC Code: 14

UKAS MANAGEMENT SYSTEMS 015

IAF

Certificate of Registration

nqa

This is to certify that the Quality Management System of

Jiangsu Jaysun Glove Co., Ltd.

Organization Code : 91321300779665160F

Operation Address : No.199, Jianling Rd., Suqian Economic Developing-Area, Jiangsu Province, China

Registered Address : No.199, Jianling Rd., Suqian Economic Developing-Area, Jiangsu Province, China

applicable to

Production and Sales of Disposable Non-sterile Vinyl(Synthetic) Examination Gloves

has been assessed and registered by NQA against the provisions of

ISO 9001:2008

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number **29206**

Date: 17 October 2013
Reissue Date: 17 May 2016
Valid Until: 14 September 2018
EAC Code: 14

UKAS MANAGEMENT SYSTEMS 015

IAF

PART II: Technical information

2.1 Standard inventory

2.2 Check table of basic requirements

2.3 Declaration of Conformity

2.1 European Union coordination and the international standard inventory.

NO.	Document Number	Version Number	Name of Document
1	ISO9001	2008	Quality control system standards-requirements
2	EN724	1995	Guidance on the Application of EN29001/EN46001 and EN29002/EN46002 for Non-active Medical device
3	MDD93/42/EEC	2007/47	Medical Device Directive
4	ISO14971	2012	Medical Device---Application of risk management to medical devices
6	EN1041	2008	Terminology，Symbols and Information with Medical Devices; Information supplied by the manufacturer with medical devices
7	ISO105-A02-	1993	Gray scale for assessing change in color

2.2 . Check table of basic requirements

Essential Requirements Check List: Appendix 1

	Content	Available /Not available	Harmonize standard	Accordance Evidence
1	The devices must be designed and manufactured in such a way that，when used under the conditions and for the purposes intended，they will not compromise the clinical condition or the safety of patients，or the safety and health of users or，where applicable，other persons，provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Available	ISO13485 and ISO 14971	Record of the quality control risk management report

2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions ,the manufacturer must apply; the following principles in the following order: -eliminate or reduce risks as far as possible(inherently safe design and construction), -where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated	Available	ISO9001 and ISO14971	See its label and risk management report

	Measures adopted			
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2)(a),as specified by the manufacturer.	Available	EN455-1 EN455-2 EN455-3	Record of the verdict of the quality management. #1, Pinhole test record. #2, Physical Test record. #3, Biocompatibility test record.
4	The characteristics and performances referred to in Sections1, 2and3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are	Available	EN455-1 EN455-2 EN455-3	Record of the consumer complain #1, Pinhole test record. #2, Physical Test record. #3,

	compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.			Biocompatibility test record.
5	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Available	EN455-4	Accelerating Ageing test record.
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. REOUIREMENTS TEGARDING DESIGN AND CONSTRUCTION 7.Chemical, physical and biological properties.	Available	ISO 14971	Risk management report
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the ‘General requirements’, Particular attention must be paid to: --the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, --the compatibility between the materials used and biological tissues, cells and body fluids, taking account of	Available	ISO14971 EN455-4 and ISO10993	#1, Accelerating Ageing test record. #2, Biocompatibility test record.

	the intended purpose of the device.			
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	Available	EN455-4 ISO14971	#1, Accelerating Ageing test record. #2, Risk management report
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	Available	EN1041 Terminology，symbols and information with Medical Devices；Information supplied by the manufacture with medical devices.	

7.4	Where a device incorporates，as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device , by analogy with the appropriate methods specified in Directive 75/318/EEC.	Not Available		
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	Not Available	/	/
7.6	Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	Available	EN374-1 EN374-2	#1, Chemicals listed. #2, SVHC of Reach chemical test. #3, MSDS file.
8.1	The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	Available	ISO13485 EN455-1 EN455-2 EN455-3	#1, Pinhole Test record. #2, Physical Test Record. #3, Chemicals Listed.

8.2	Tissues of animal origin must originate form animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	Not Available	/	/
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	Not Available		
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	Not Available		
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	Not Available		

8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Not Available		
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Not Available		
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	Available	ISO 14971	Risk management report
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: - the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, -risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences,	Available	ISO 14971	#1, Risk management report. #2, Customers Satisfaction Questionnaire.

	electrostatic discharge, pressure, temperature or variations in pressure and acceleration, -the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, -risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
9.3	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	Available	ISO 14971	#1, Risk management report. #2, Customers Satisfaction Questionnaire.
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	Not Available		
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	Not Available		

10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181 EEC (1).	Not Available		
11.1	Devices shall be designed and manufactured in such w way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application go appropriate specified levels for therapeutic and diagnostic purposes.	Not Available		
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	Not Available		
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Not Available		

11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended , stray or scattered radiation is reduced as far as possible.	Not Available		
11.4	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Not Available		
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, Geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Not Available		
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such w way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	Not Available		
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type	Not Available		

	and energy and where appropriate the quality of radiation.			
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	Not Available		
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	Not Available		
12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Not Available		
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death to severe deterioration of the patient’s state of health.	Not Available		
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or	Not Available		

	equipment in the usual environment.			
12.6	Protection against electrical risks. Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	Not Available		
12.7.1	Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	Not Available		
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means apply for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	Not Available		
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means apply to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	Not Available		

12.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	Not Available		
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	Not Available		
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	Not Available		
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	Not Available		
12.9	The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and,	Not Available		

	as appropriate, the patient.			
13.1	Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or II a if they can be used safely without any such instructions.	Available	ISO 14971	#1, Training users to use products correctly, #2, Usage method
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colors used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colures must	Available		Labels on packages, and the storage instructions.

	be described in the documentation supplied with the device.			
13.3	The label must bear the following particulars:			
a.	The name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14(2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;	Available	EN 980 EN 1041	See its label
b.	The details strictly necessary for the user to identify the device and the contents of the packaging;	Available	EN455-4	Aging test record
c.	Where appropriate, the word ‘STERILE’;	Not Available		
d.	Where appropriate, the batch code, preceded by the word ‘LOT’,or the serial number;	Available	EN455-4	Aging test record
e.	Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	Available	EN455-4	Aging test record

f.	Where appropriate, an indication that the device is for single use;	Available	/	Single use
g.	If the device is custom-made, the words ‘custom-made device’;	Not Available	/	/
h.	If the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;	Not Available	/	/
i.	Any special storage and/or handling conditions;	Available	EN 1041	its label
j.	Any special operating instructions;	Available	/	/
k.	Any warnings and/or precautions to take;	Available	EN 1041	Label and Usage method
i.	Year of manufacture for active devices other than those covered by(e).This indication may be included in the batch or serial number;	Not Available	/	/
m.	Where applicable, method of sterilization.	Not Available	/	/
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Available	/	Medical or Industry filed.
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Available	/	Local product record regulation
13.6	Where appropriate, the instructions for use must	Not Available		

	contain the following particulars:			
a.	the details referred to in Section 13.3, with the exception of(d)and(e);	Not Available		
b.	The performances referred to in Section 3 and any undesirable side-effects;	Available	EN1041 EN 3039	See its label
c.	If the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	Not Available		
d.	All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;	Not Available		
e.	Where appropriate, information to avoid certain risks in connection with implantation of the device;	Not Available		
f.	Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	Available	EN1041 EN 3039	See its label

g.	The necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	Not Available		
h	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I;	Not Available		
I	Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	Not Available		
J	In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:	Not Available		

K	Precautions to be taken in the event of changes in the performance of the device;	Available		
l	precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	Available	EN 3039	
m.	adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	Available		
n.	Precautions to be taken against any special , unusual risks related to the disposal of the device;	Available		As per the disposal instructions
o.	medicinal substances incorporated into the device as an integral part in accordance with Section 7.4;			

p	Degree of accuracy claimed for devices with a measuring function.			
14	Where conformity with the essential requirements must be based on clinical data, as in Section I (6), such data must be established in accordance with Annex X.			

2.3. Declaration of Conformity.

CERTIFICATE
of Conformity

TÜVRheinland®

Registration No.: AK 60092865 0001

Report No.: 21213667 001

Holder: Jiangsu Jaysun Glove Co., Ltd.
No. 199 Jianling RD, Economic Development Zone
Sugian City
223800 Jiangsu
China

Product: Protective gloves
according EN 455 part 1, 2 and 3

Identification: P-102 Disposable Vinyl (synthetic) Examination Gloves

type: Synthetic Examination Glove, powder free, for single use
size: S - XL
material: Vinyl
AQL: 2,5

Tested acc. to: EN 455-1:2000
DIN EN 455-2/05.11
EN 455-3:2006
EN 420:2003-A1

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

Certification Body

Dipl.-Ing. C. Albrecht

Date 24.03.2014

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Part III: Risk Analysis Report

The medical device risk management report

1 Foreword

This text is the report that carries on the risk management to the **JIANGSU JAYSUN GLOVE CO., LTD**, in the report to some relevant of the possible harm and each reason of the harm produce on judge. And evaluate some relevant severity and the occurrence of the harm. If the risk level can't accept, adopt to lower to see of control measure, carry on an evaluation towards adopting the risk measure after of residual risk in the meantime. Last, making some relevant levels of residual risk can accept.

2 Apply scope

This report is applicable to the **JIANGSU JAYSUN GLOVE CO., LTD** products, that product are produced from mainly PVC pastes and phthalates.

The products will mainly use in the Medical and Industry fields.

3 Application data

3.1 Related standards

3.2 The data concerning product

1) Application of the ISO14971:2012--medical device-application of risk management to the medical device
2) The standard of product and other

1) The clinic use circumstance, maintain a record, the customer complain, emergence record etc.

There are no such relevant data.

2) The article in the professional literature and other information

Refer to the relevant document published in the authority web of EU

3.3 Abbreviation words explain:

1) FMEA: The expired mode and effect analysis
2) FMECA: The expired mode, effect and the harm degree analyze;
3) FTA: Top-Down the tree analysis etc.;
4) SEEA: software errors affect analysis

4 The product explain

4.1 Use environments

Everybody without who are probably sensitive to them can use them anywhere at any environments.

4.2 The related data of risks evaluation and information

People who are allergic to the products cannot use this product, and the products also cannot be used for sterile environment. Products cannot be used in the Environments when maybe cause harm to people.

For detail please refer to relevant data published in the authority journal.

5 The explain of risk management

5.1 General

The object of this risk management is a document used to lower the risk which maybe occur without it and help to risk control

5.2 Functions explain

If the see of behind insurance lowers control measure to need to have understanding to some functions, should do an elucidation to the related function.

5.3 Intended purpose

Lower the risk and help to risk control

5.4 Use environment

During the process of the produces product

5.5 The risk evaluates the related data and information

6 The execute of the risk management process

6.1 Intended purpose judge

To protect the body especially for withstand tears and abrasions

6.2 Judge of the harm known and can be foresee

(ITEM)	(CONTENTS)	Available	NOT Available
II.2-1	Electricity		Not Available
II.2-2	Heat		Not Available
II.2-3	Mechanical force	Available	
II.2-4	Ionizing radiation		Not Available
II.2-5	Non-ionizing radiation		Not Available
II.2-6	Moving parts		Not Available
II.2-7	Unintended motion		Not Available
II.2-8	Suspended masses		Not Available
II.2-9	Patient support device	Available	
II.2-10	Pressure (vessel rupture)		Not Available
II.2-11	Acoustic pressure		Not Available
II.2-12	Vibration		Not Available
II.2-13	Electromagnetic fields		Not Available

II.3 Biological hazards ☐ Available ☐ Not Available

(ITEM)	(CONTENTS)	Available	NOT Available
II.3-1	Bio-contamination	Available	
II.3-2	Bio-incompatibility	Available	
II.3-3	Incorrect formulation(chemical composition)	Available	
II.3-4	Toxicity	Available	
II.3-5	Mutagenicity	Available	

II.3-6	Oncogenicity	Available	
II.3-7	Teratogenicity	Available	
II.3-8	Carcingenicity	Available	
II.3-9	(cross-)Infection	Available	
II.3-10	Pyrogenicity	Available	
II.3-11	Inability to maintain hygienic safety	Available	
II.3-12	Degradation	Available	

II.4 Environmental hazards ☐Available ☐ Not Available

(ITEM)	(CONTENTS)	Available	NOT Available
II.4-1	Electromagnetic interference		Not Available
II.4-2	Inadequate supply		Not Available
II.4-3	Restriction of cooling		Not Available
II.4-4	Storage or operation outside prescribed environmental condition	Available	
II.4-5	Incompatibility with other devices	Available	
II.4-6	Accidental mechanical damage	Available	
II.4-7	Contamination due to waste products and/or device disposal	Available	

II.5 (Hazards related to the use of the device)

(ITEM)	(CONTENTS)	Available	NOT Available
II.5-1	Inadequate Labeling		Not Available
II.5-2	Inadequate operating instructions		Not Available
II.5-3	Inadequate specification of accessories		Not Available
II.5-4	Inadequate specification of pre-use check		Not Available
II.5-5	Over-complicated operating instructions		Not Available
II.5-6	Inadequate specification of service and maintenance		Not Available
II.5-7	Use by unskilled/untrained personnel	Available	
II.5-8	Human error	Available	
II.5-9	Insufficient warning of side effects	Available	
II.5-10	Insufficient warning of hazards likely with re-use of single use devices	Available	
II.5-11	Incorrect measurement and other metrological aspects		Not Available

II.5-12	Incompatibility with consumables/accessories/other medical devices		Not Available
II.5-13	Sharp edges or points		Not Available

II.6 (Hazard arising from functional failure, maintenance and aging):

ITEM	CONTENTS	Available	NOT Available
II.6-1	Erroneous data transfer		Not Available
II.6-2	Lack of specification for maintenance		Not Available
II.6-3	Inadequately maintenance		Not Available
II.6-4	Lack of adequate determination of end of device life		Not Available
II.6-5	Loss of electrical mechanical integrity		Not Available
II.6-6	Inadequate packaging (contamination and/or deterioration of the device)	Available	
II.6-7	Re-use and/or improper-use	Available	
II.6-8	Deterioration in function	Available	

(Others):

ITEM	CONTENTS	Available	NOT Available
no	no	/	/

In sum, the medical use vinyl gloves which our factory produced, its use value of the medical use is far greater than the risk, can serve as medical equip.

Part Ⅳ: Test Report of ISO 10993 regarding of Biological Evaluation of Medical Devices

The Biological Evaluation Test reports include Dermal Sensitivity Testing, Primary Skin Irritation Testing, as well as Vitro Cytotoxicity Report; the relative report can be finding as below:

4.1 : Demarl Sensitivity Testing (is in updating):

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Life Science Services Laboratory

T:021-61152161, 61152160 F:021-64951517
中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼
7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

Test Report

Date: 18th Sep. 2015

Client name: JIANGSU JAYSUN GLOVE CO., LTD

Client address: No.199 Jianling Rd. Economic Developing-Area, Suqian City, Jiangsu Province

Assignment ID: 14A1502152

Sample No.: 14S15009148

Report on the submitted sample identified by the client as below:

Product Name	Vinyl (Synthetic) Examination Gloves
Quantity Received	1 bag
Batch No.	PWM
Manufacturer	JIANGSU JAYSUN GLOVE CO., LTD
Sample Receiving Condition	Room temperature
Sample Receiving Date	19th Jun.2015
Testing Period	24th Jul.2015 – 21st Aug.2015

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The test was carried out by SGS subcontractor certified ISO 17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

May Ding
Life Science Quality Assurance
Authorized Signature

Attachment 1: Test for skin sensitization (Maximization test)

SUMMARY

A guinea pig maximization test of the test article, Vinyl (Synthetic) Examination Gloves, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices part 10: Tests for irritation and skin sensitization; ISO10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five reagent control guinea pigs (per vehicle). Following a recovery period, the test and reagent control animals were received a challenge patch of the appropriated test article extract and the reagent control. All sites were scored at 24 h and 48 h after patch removal.

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

MATERIALS

The test article was provided by the sponsor was identified and handled as follows:

Test Article:	Vinyl (Synthetic) Examination Gloves
Storage Conditions:	Room temperature
Extraction Vehicle:	0.9% sodium chloride injection (SC) Cotton seed oil (CSO)
Test Article Preparation:	According to the requirement of the sponsor, the test articles were sterilized at 121 ℃ for 30 min before the treatment. Based on the ISO ratio of 6 cm^2:1 ml [Surface area of the test article to volume of extraction vehicle], 96 cm^2 of the test article was covered with 16 ml of extraction vehicle under aseptic conditions for preparing the SC

and CSO test extract at 37 ℃ for 72 h respectively for each phase. The extracts were used after extraction.

Reagent Control: The vehicles (without test article) were similarly prepared to serve as the reagent control.

Condition of extracts: All the extract of the test and controls were clear.

Additional materials: Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the vehicle.
A 10% (w/w) sodium dodecyl sulphate suspension in paraffin.

In addition according ISO10993-10 requirement, 5% mercaptobenzothiazole (dissolved in DMSO) as a positive control was used previously for another study last three months. Complete data is traceable in laboratory records.

METHODS

Test System

Species:	Albino guinea pig
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FEILD
Sex:	Male
Body Weight Range:	307.2 g to 350.3 g
Age:	Young adult
Number of animals:	Thirty

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from SHANGHAI SLAC LABORATORY ANIMAL CO. LTD.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 5 days before the treatment, and then they were individually housed in stainless

steel suspended cages identified by a card indicating the Identification No. of the test article and first treatment date.

Environmental: The room temperature and humidity were monitored daily. The temperature range for the room was from 23 ℃ to 26 ℃. The room humidity range was from 55% to 63%.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, unused animals were selected.

Experimental Procedure:

1. Intradermal induction phase (induction I):

The day prior to treatment, the fur was clipped on all treatment sites with an electric clipper. The 1st day, the test animals were injected with the fresh extracts of test article and the control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2 cm x 4 cm boundary of the fur clipped area as illustrated below:

Cranial

a	a
b	b
c	c

Caudal

Test Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
b) 0.1ml of test extract
c) 0.1ml of 50:50(v/v) mixture of a and b

Control Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the vehicle
b) 0.1ml of vehicle
c) 0.1ml of 50:50(v/v) mixture of a and b

2. Topical induction phase (Induction II):

At 7th day after completion of the intradermal induction phase, the same area was clipped free of fur and treated with 10% sodium dodecyl sulphate suspension in paraffin. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered.

At 8th day, a 20mm×40mm section of absorbent gauze patch, saturated with freshly prepared the extract of the test article, and then was topically applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate reagent control. Each patch was secured with an occlusive dressing. The dressings and patches were removed after 48h.

3. Challenge phase

At 22nd days, the fur was removed from the left flank areas. At 23rd day, absorbent gauze patches were soaked with the corresponding solution at the concentration of site C, and patched on the left upper flank of each animal in test and reagent control group. Then the animals were secured with an occlusive dressing. The dressings and patches were removed after 24 h.

4. Observation of animals

The appearance of the challenge skin sites of the test and control animals was observed respectively at 24 h and 48 h after removal of the dressing. The skin reactions for erythema and swelling were described and graded in according with the criteria shown below:

Patch test reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

If the grades of less than 1 are seen in reagent control animals, grades of 1 or greater in the test group were generally indicated sensitization.

RESULTS

Clinical Observation:

All animals appeared clinically normal throughout the study.

Dermal Observations:

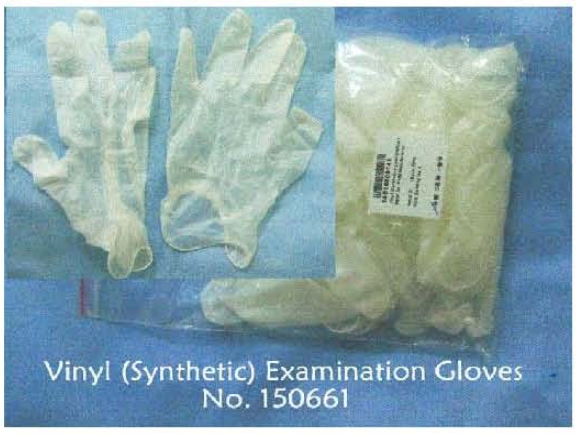
No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase shown below:

	Hours following patch removal			
Time	24 h		48 h	
Vehicle	SC	CSO	SC	CSO
Test article	0	0	0	0
Reagent Control	0	0	0	0

CONCLUSION

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article sample tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center
Life Science Services Laboratory

3rd Building No.889 Yishan Road Xuhui District, Shanghai, China 200233 t(86-21)61152197 f(86-21)64951517 www.cn.sgs.com

中国·上海徐汇区宜山路889号3号楼 邮编：200233 t(86-21)61162197 f(86-21)64961617 sgs.china@sgs.com

4.2: Primary Skin Irritation Testing (is in updating):

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Life Science Services Laboratory

T:021-61152161, 61152160 F:021-64951517
中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼
7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

Test Report

Date: 27th Jul. 2015

Client name: JIANGSU JAYSUN GLOVE CO., LTD

Client address: No.199 Jianling Rd. Economic Developing-Area, Suqian City, Jiangsu Province

Assignment ID: 14A1502152

Sample No.: 14S15009148-01

Report on the submitted sample identified by the client as below:

Product Name	Vinyl (Synthetic) Examination Gloves
Quantity Received	1 bag
Batch No.	PWM
Manufacturer	JIANGSU JAYSUN GLOVE CO., LTD
Sample Receiving Condition	Room temperature
Sample Receiving Date	19th Jun.2015
Testing Period	3rd Jul.2015 – 10thJul.2015

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The test was carried out by SGS subcontractor certified ISO17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

May Ding
Life Science Quality Assurance
Authorized Signature

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center
Life Science Services Laboratory

3rd Building No.889 Yishan Road Xuhui District, Shanghai, China 200233 t(86-21)61152197 f(86-21)64951517 www.sgsgroup.com.cn
中国.上海.徐汇区宜山路 889 号 3 号楼 邮编: 200233 t(86-21)61152197 f(86-21)64951517 sgs.china@sgs.com

CHLC 94679

Attachment 1: Test for irritation (Animal skin irritation test)

SUMMARY

The animal skin irritation test of the test article, Vinyl (Synthetic) Examination Gloves, was conducted to assess the potential of the material to produce irritation. This study was conducted based on the requirements of the International Organization for Standardization ISO 10993-10: 2010: Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization. ISO 10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton oil (CSO). Each extract and corresponding reagent control was contacted on animal skin directly. Observations for erythema and edema were conducted at 24, 48 and 72 hours after contact.

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The Primary Irritation Index Characterization for the test article was negligible.

MATERIALS

Test Article:	Vinyl (Synthetic) Examination Gloves
Storage Conditions:	Room temperature
Extraction Vehicle:	0.9% sodium chloride injection (SC) Cotton seed oil (CSO)
Test Article Preparation:	Based on the ISO ratio of 6 cm^2: 1 ml [Surface area of the test sample to volume of extraction vehicle], 90 cm^2 of the test articles were covered with 15 ml of extraction vehicle for preparing the SC and CSO test extract at 37℃ for72 h respectively. The extracts were used after extraction.
Reagent Control:	The extraction vehicles (without test article) were similarly prepared to serve as the reagent control.
Condition of extracts:	All the extract of the test and controls were clear.

SGS-CSTC Standards Technical Services Co., Ltd. Shanghai Testing Center
Life Science Services Laboratory

SHLS 094680

3rd Building No.889 Yishan Road Xuhui District, Shanghai, China 200233 t(86-21)61152197 f(86-21)64951517 www.cn.sgs.com
中国.上海.徐汇区宜山路 889 号 3 号楼 邮编：200233 t(86-21)61152197 f(86-21)64951517 sgs.china@sgs.com

In addition according ISO 10993-10 requirement, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study last two months. Complete data is traceable in laboratory records.

METHODS

Test System:

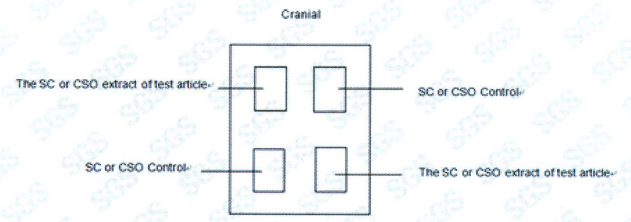
Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Male
Body weight range:	2.2 kg ~ 2.5 kg
Age:	Young adult
Number of animals:	Six

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities".
Food:	Diet was provided from SHANGHAI SLAC LABORATORY ANIMAL CO. LTD
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment，and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No of the test article and first treatment date.
Environmental:	The room temperature and humidity was monitored daily. The room temperature range was from 21℃ to 23℃. The room humidity range was from 57% to 62%.
Personnel Selection:	Associates involved were appropriately qualified and trained. Only healthy, previously unused rabbits were selected.

Experimental Procedure:

On the day before the test, each rabbits were closely clipped the fur on the backs of the animals, and both sides of the spinal for application and observation of all test sites, approximately 10 cm x15 cm. A 25 mm×25 mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to the test sites. The extract of test article and the reagent control were directly applied to the region as illustrated below:



The application sites were covered with a gauze patch and then the application sites were wrapped with a semi-occlusive bandage for 24 h. At the end of the contact time, the dressings were removed. A natural lighting was used to visualize the skin reactions. The skin reactions for erythema and oedema were described and scored at 1, 24, 48 and 72 hours.

The tissue reaction for erythema and oedema were graded according to the classification system given below for each site and at each time observed, and the results were recorded.

Reaction	Primary Irritation Score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4

Reaction	Primary Irritation Score
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-define by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4

Only the 24, 48 and 72hours observations were used for calculation. For each animal, the score both erythema and oedema at each time point were added together separately for each test article and the negative control. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (2 test sites x 3 time points). All the primary irritation scores of individual animals were added and divided by the number of animals, and then the primary irritation scores for each test article were obtained. A similar calculation was made with the negative control. The primary irritation index was obtained by subtracting the score of the negative control from the test article score and the response categories were given as below:

Mean score	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

RESULTS

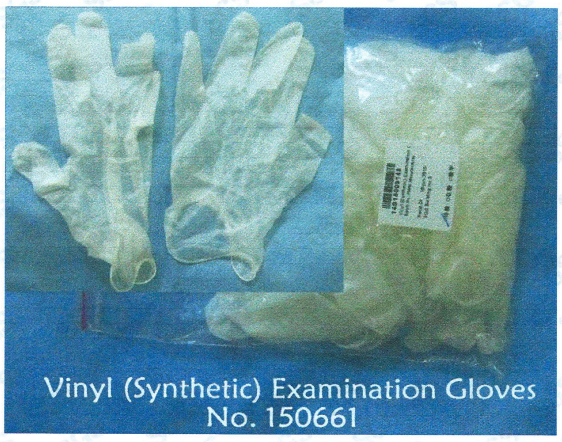
All animals appeared clinically normal throughout the study. All sites of the test extract and the reagent control appeared normal following removal the patches; the score of the test extract and the reagent control all were 0.

The Primary Irritation Index (PII) of the test article was all 0.0.

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The Primary Irritation Index Characterization for the test article was negligible.

PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article sample tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

Part V: Part V: Chinese FDA certificates & GMP Inspection

5.1. The Certificate of Chinese Food&Drag Administration on the Meidcal Device and

宿迁市第一类医疗器械备案信息表

备案号：苏宿械备 20150001 号

备案人名称	江苏杰盛手套有限公司
备案人组织机构代码	77966516-0
备案人注册地址	江苏省宿迁经济技术开发区建陵道 199 号
生产地址	江苏省宿迁经济技术开发区建陵道 199 号
产品名称	检查手套
型号/规格	XS 、S、 M、 L、 XL、XXL
产品描述	医疗检查过程中戴于检查者手部的用品。(检查手套采用 PVC 树脂粉、DINP、稳定剂、降粘剂等制成，分有粉和无粉两种，有粉检查手套是在手套定型后在手套表面涂改良玉米淀粉，无粉检查手套是手套定型后在手套表面涂一层水性 PU 试剂。)
预期用途	用于防止医生与患者之间的交叉感染。
备注	—
备案单位和日期	宿迁市食品药品监督管理局 备案专用章 备案日期 2015 年 02 月 11 日
变更情况	—

5.2. The GMP of the Inspection Result of Chinese Government.

Jiangsu Jaysun Glove Co., Ltd.
No.199 Jiangling Rd, Suqian City, Jiangsu, China 223800
Tel: 86-527-8831-9931, Fax: 86-527-8831-9289

Medical Device GMP Inspection Result Notice

Manufacturer: JIANGSU JAYSUN GLOVE CO., LTD

Registration Address: No. 199 Jianling Road, Suqian City, Jiangsu Province, China 223800

Production Address: No. 199 Jianling Road, Suqian City, Jiangsu Province, China 223800

Products: Disposable vinyl gloves, powdered and powder free. Size: XS, S, M, L, XL and XXL

Base on "Medical Device Good Manufacturing Practice (Trial)" and the relevant implementing rules for medical deivice GMP inspection, the inspection concluded that: PASS.

JIANGSU JAYSUN GLOVE CO., LTD

Part VI: Test Report:

Sample Name	Inspection Item	Results	Inspection Standard
Disposable Vinyl Examination Gloves	Freedom form Holes Dimensions	Inspect 80 pairs, no water leakage On page 2	EN455-1:2000 EN455-2:2000
	Force at break	3.6N, Pass	EN455-2:2000
	Force at break of seam	3.6N, Pass	EN455-2:2000
	Force at beak(Aged)	3.6N, Pass	EN455-2:2000
	Force at break of seam(Aged)	3.6N, Pass	EN455-2:2000

Dimensions of disposable vinyl (synthetic) examination gloves Size L

NO.	Length(mm)	Width(mm)
1	242	106
2	241	105
3	242	105
4	242	105
5	240	104
6	241	104

7	245	105
8	243	105
9	242	105
10	242	107
11	241	103
12	241	105
13	242	105

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