

Doc. No. CE-01 V1.0

Technical Construction File

Product Name: Disposable Vinyl Examination Gloves

According to 93/42/EEC

2019-2



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1. Introduction of the Manufacturer

1.1 Introduction of the Company

Jiangsu Dingjie Medical Equipment Co., Ltd. was founded in 2017, is a professional production of PVC gloves factory. The 4 existing production lines, later gradually extended to 12 production lines, annual output is expected to reach 1 billion 600 million glove. The products include PVC series and PE series gloves. Products can be widely used in medical and health, laboratory, food processing, food and beverage hotel, electronic industry, household daily, hotel catering and other fields. Products on the human body skin without allergic reaction, nontoxic, harmless, tasteless, anti penetration, acid and alkali, anti oil. We have a strict management system to ensure product.

1.2 Basic information of the Manufacturer

Manufacturer: Jiangsu Dingjie Medical Equipment Co., Ltd.

Address: No.219 Yanjiang Road, Changjiang Town, Rugao City, Nantong City, Jiangsu Province, China

TEL: 13914158868

2. Product introduction

Our company produces Disposable Vinyl Examination Gloves. Products can be widely used in medical and health, laboratory, food processing, food and beverage hotel, electronic industry, household daily, hotel catering and other fields. Products on the human body skin without allergic reaction, nontoxic, harmless, tasteless, anti penetration, acid and alkali, anti oil.

2.1 Product classification

Classification: According to the classification rule 1 in MDD93/42/EEC Annex IX, the above product is Class I medical device.

2.2 Certification mode

The selected conformance certification mode is Annex VII.

3. Comprehensive description of product

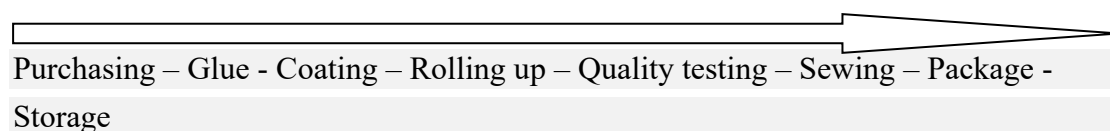
3.1 Product photos and specifications

3.1.1. Photos



3.2 Production flow chart

Disposable inspection gloves



3.3 Product transportation and storage

Transportation

General traffic tools available transportation, but must prevent the transport process should prevent severe impact, vibration, and the rain and snow shower splash. Transportation demanded by the order of the contract.

Storage


Store at room temperature.

4. Product label and language requirements

4.1 Design of label

The product produced by our company labeled with the following information:

a. Product name, type and quantity;

b.  CE mark: pieced with two semi-circles with its diameter no less than 5mm;

c. Batch number  DATE OF MANUFACTURE .

d. “DO NOT REUSE”, “SINGLE USE”, “USE ONLY ONCE”  ;

e. Manufacturer name .

f. Manufacturer address, telephone number and fax number;

g. Name and address of the EC representative .

4.2 According to the requirements of MDD93/42 EEC, the medical products supplied to European market should be labeled in line with the specification.

4.2.1 The identify content:

Product name and Quantity, Type

Attaching CE marking indicates that:

This device meets the basic requirements of MDD.

This device has passed a relevant conformity estimation program.

There are two types of CE Marking attached on the medical devices: CE marking without identified number of Notified Body and CE marking with identified number of Notified Body. CE marking without identified number only apply to the Class I medical devices, which needn't to be sterilized and have no measure function.

4.2.2 Languages on labels shall be in line with the language requirements of European Union member countries (see the following table) and accuracy of the languages should be guaranteed.









Language Requirements for Labeling in the EU Member States

Country \ Language	Denish	Dutch	English	Finnish	French	German	Greek	Icelandic	Italian	Norwegia	Portugues	Spanish	Swedish	Czech	Estonian	Russian	Hungarian	Latvian	Lithuania	Polish	Slovak	Slovesne
Austria						★																
Belgium		★			★	★																
Denmark	★																					
Finland				★									★									
France					★																	
Germany						★																
Greek							★															
Holland		★																				
Iceland								★														
Ireland			★																			
Italy									★													
Luxembourg					★	★																
Norway										★												
Portugal											★											
Spain												★										
Sweden													★									
Switzerland					★	★																
United Kingdom			★																			
Cyprus							★															
Czech														★								
Estonia			★												★	★						
Latvia			★													★		★				
Lithuania																			★			
Malta			★																			
Poland																				★		
Slovakia																					★	
Slovenia																						★
Hungary																	★					

4.3 Special requirements:

In addition to meet the special requirement of the clients about the label, if they had, the left content should be designed as the above.

4.4 Please refer to the following samples of labels.

Product Name	Type:
	
 Lot Number:	Quantity:
 20190201	 20220131
 Jiangsu Dingjie Medical Equipment Co., Ltd. No.219 Yanjiang Road, Changjiang Town, Rugao City, Nantong City, Jiangsu Province, China	
	
	

5. Checklist of Essential requirements

According to the requirements for Annex I of MDD93/42/EEC “Medical polymer cast and splint”, the checklist of essential requirements lists the standards and documents for compliance with the legal requirements. It can provide sufficient evidence to meet the requirements of the Annex I. The following are the EU harmonized/international standards and checklist of essential requirements.

5.1 List of EU harmonized standards

Standards	Document Title
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2012	Graphical symbols for use in the labeling of medical devices
EN 455-1:2000	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
EN 455-2:2009+A2:2013	Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3:2006	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

5.2 Checklist of essential requirements

**Essential requirements according to the Directive 93/42/EEC
(including 2007/47/EC) related to medical devices.**

Type and name of the product: *Disposable Vinyl Examination Gloves*

Class of the product: Class I

Classification rule(s): Rule 1

Date and signature: 2019/2/1

	Applicant
Name	Jiangsu Dingjie Medical Equipment Co., Ltd.
Address	No.219 Yanjiang Road, Changjiang Town, Rugao City, Nantong City, Jiangsu Province, China
Contact	
Telephone	
Fax	
E-mail	

The requirement of Medical Device Directive 93/42/EEC(including 2007/47/EC)	Applicable	Standard	Evidence of Conformity
<p>I. GENERAL REQUIREMENTS</p> <p>The device 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.</p> <p>This shall include:</p> <ul style="list-style-type: none"> — reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and — consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>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:</p> <ul style="list-style-type: none"> — 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, — inform users of the residual risks due to any shortcomings of the protection measures adopted. 	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>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.</p>	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>4. The characteristics and performances referred to in Sections 1, 2 and 3 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 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.</p>	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>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.</p>	A	ENISO 14971 ENISO 10993 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>6. Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.</p>	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X</p>	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>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:</p> <ul style="list-style-type: none"> — the choice of materials used, particularly as regards toxicity 	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU

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and, where appropriate, flammability, — the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device, — where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.			
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.	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
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.	A	ENISO 14971 ENISO 455 ENISO 15223-1	Risk analysis report Test report Label IFU
<p>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 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.</p> <p>For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (1) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.</p> <p>Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.</p> <p>Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.</p> <p>When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the</p>	NA		

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established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.			
<p>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. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances.</p> <p>If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.</p> <p>If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.</p>	NA		
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.	NA		
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.	NA		
<p>8.2 Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.</p> <p>Notified bodies shall retain information on the geographical origin of the animals.</p> <p>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.</p>	NA		
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.	NA		
8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	NA		
8.5 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	NA		

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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.	NA		
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.	NA		
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.	NA		
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 ration, dimensional and where appropriate ergonomic features, — risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, — the risks of reciprocal interference with other devices normally used in the investigations of for the treatment given, — Risks arising when maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	NA		
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 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	NA		
10 Devices with a measuring function 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.	NA		
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.	NA		
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.	NA		
11.1 General 11.1.1 Devices shall be designed and manufactured in such a 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 of appropriate specified levels for therapeutic and diagnostic purposes.	NA		
11.2 Intended radiation 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.	NA		

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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.	NA		
11.3 Unintended radiation 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.	NA		
11.4 Instructions 11.4.1 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 of eliminating the risks inherent in installation.	NA		
11.5 Ionizing radiation 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.	NA		
11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	NA		
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 and energy and where appropriate the quality of radiation.	NA		
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.	NA		
12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	NA		
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.	NA		
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.	NA		
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 or severe deterioration of the patient's state of health.	NA		
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 equipment in the usual environment.	NA		
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.	NA		

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12.7 Protection against mechanical and thermal risks 12.7.1 Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risk connected with, for example, resistance, stability and moving parts.	NA		
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 available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	NA		
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 available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	NA		
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.	NA		
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.	NA		
12.8 Protection against the risks posed to the patient by energy supplies or substances 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.	NA		
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.	NA		
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, as appropriate, the patient.	NA		
13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. 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 IIa if they can be used safely without any such instructions.	A	ENISO 15223-1	Label

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13.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	A	ENISO 15223-1	Label
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 the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community;	A	ENISO 15223-1	Label
b) the details strictly necessary for the user to identify the device and the contents of the packaging;	A	ENISO 15223-1	Label
c) where appropriate, the word 'STERILE';	NA		
d) where appropriate, the batch code, preceded by the work 'LOT', or the serial number;	A	ENISO 15223-1	Label
e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and the month;	A	ENISO 15223-1	Label
F) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;	A	ENISO 15223-1	Label
G) if the device is custom-made, the words 'custom-made device';	NA		
H) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	NA		
I) any special storage and/or handling conditions;	NA		
J) any special operating instructions;	NA		
K) any warnings and/or precautions to take;	A	ENISO 15223-1	Label
L) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	NA		
M) where applicable, method of sterilization.	NA		
N) in the case of a device within the meaning of Article 1 (4a), an indication that the device contains a human blood derivative.	NA		
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.	A	ENISO 15223-1	Label
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.	A	ENISO 15223-1	Label
13.6 Where appropriate, the instructions for use must contain the following particulars: a) the details referred to in Section 13.3, with the exception of (d) and (e);	A	ENISO 15223-1	Label
b) the performances referred to in Section 3 and any undesirable side-effects;	A	ENISO 15223-1	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;	NA		

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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;	NA		
e) where appropriate, information to avoid certain risks in connection with implantation of the device;	NA		
f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment	NA		
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	NA		
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; If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;	NA		
i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	NA		
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:	NA		
k) precautions to be taken in the event of changes in the performance of the device;	A	ENISO 15223-1	Label
l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	NA		
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;	NA		
n) precautions to be taken against any special, unusual risks related to the disposal of the device;	NA		
o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	NA		
p) degree of accuracy claimed for devices with a measuring function.	NA		
q) date of issue or the latest revision of the instructions for use.	A	ENISO 15223-1	IFU

6. Risk management report

Company name:	Jiangsu Dingjie Medical Equipment Co., Ltd.
Company Address:	No.219 Yanjiang Road, Changjiang Town, Rugao City, Nantong City, Jiangsu Province, China
Product:	Disposable Vinyl Examination Gloves
Model:	9 inch, Powder free, Clear Color 9 inch, Powdered, Clear Color 9 inch, Powder free, Blue Color 9 inch, Powdered, Blue Color 9 inch, Powder free, Yellow Color 9 inch, Powdered, Yellow Color
Accessories:	N/A
Procedure:	EN ISO14971:2012
Result:	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Identification of qualitative and quantitative characteristics (acc. to EN ISO 14971:2012, cl. 4.2)

No.	Questions	Answer
1	What is the intended use and how is the medical device to be used?	Protecting wound. It is applied to wrist, knee, waist and other body parts.
2	Is the medical device intended to be implanted?	No.
3	Is the medical device intended to be in contact with the patient or other persons?	Yes, Products and the surface of intact human skin contact, the contact time is short, not harmful to humans
4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Main raw materials for the non-woven products in testing, product testing materials, meet the health standards
5	Is energy delivered to or extracted from the patient?	No.
6	Are substances delivered to or extracted from the patient?	No.
7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No.
8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No.
9	Is the medical device intended to be routinely cleaned and disinfected by the user?	No.
10	Is the medical device intended to modify the patient environment?	No.
11	Are measurements taken?	No.
12	Is the medical device interpretative?	No.
13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No.
14	Are there unwanted outputs of energy or substances?	No.
15	Is the medical device susceptible to environmental influences?	Products in the transport and storage should be attention to moisture, so as not to affect the use of the product effect
16	Does the medical device influence the environment?	No.
17	Are there essential consumables or accessories associated with the medical device?	No.
18	Is maintenance or calibration necessary?	No.
19	Does the medical device contain software?	No.
20	Does the medical device have a restricted shelf-life?	2 years.
21	Are there any delayed or long-term use effects?	To extend the use of the product may affect the products quality, and it will affect the user's health

Jiangsu Dingjie Medical Equipment Co., Ltd.

22	To what mechanical forces will the medical device be subjected?	No.
23	What determines the lifetime of the medical device?	No.
24	Is the medical device intended for single use?	Yes.
25	Is safe decommissioning or disposal of the medical device necessary?	No.
26	Does installation or use of the medical device require special training or special skills?	No.
27	How will information for safe use be provided?	See product lable.
28	Will new manufacturing processes need to be established or introduced?	No.
29	Is successful application of the medical device critically dependent on human factors such as the user interface?	No.
29.1	Can the user interface design features contribute to use error?	No.
29.2	Is the medical device used in an environment where distractions can cause use error?	No.
29.3	Does the medical device have connecting parts or accessories?	No.
29.4	Does the medical device have a control interface?	No.
29.5	Does the medical device display information?	No.
29.6	Is the medical device controlled by a menu?	No.
29.7	Will the medical device be used by persons with special needs?	No.
29.8	Can the user interface be used to initiate user actions?	No.
30	Does the medical device use an alarm system?	No.
31	In what way(s) might the medical device be deliberately misused?	No.
32	Does the medical device hold data critical to patient care?	No.
33	Is the medical device intended to be mobile or portable?	No.
34	Does the use of the medical device depend on essential performance?	No.

Risk Analysis Jiangsu Dingjie Medical Equipment Co., Ltd.

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				

D2. Energy Hazards										
1	Electricity	N/A								
2	Heat	N/A								
3	Mechanical force	N/A								
4	Ionizing radiation	N/A								
5	Non-ionizing radiation	N/A								
6	Electromagnetic fields	N/A								
7	Moving parts	N/A								
8	Suspended masses	N/A								
9	Patient support device failure	N/A								
10	Pressure(vessel rupture)	N/A								
11	Acoustic pressure	N/A								
12	Vibration	N/A								
13	Magnetic fields(e.g. MRI)	N/A								
D3. Biological hazards										
1	Bio-contamination	N/A								
2	Bio-incompatibility	Product may cause the user infected.	1	1	1	1	There is warning information on the Label and IFU.	EN ISO 10993 Test report	No	Yes

Risk Analysis Jiangsu Dingjie Medical Equipment Co., Ltd.

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
3	Incorrect formulation(chemical composition)	N/A								
4	Toxicity	Allergic people may come out in a rash or have abnormal sensation.	1	1	1	1	There is warning information on the Label and IFU.	EN ISO 10993 Test report	No	Yes
5	Allergen city	N/A								
6	Mutagenicity	N/A								
7	Oncogenicity	N/A								
8	Teratogenicity	N/A								
9	Carcinogenicity	N/A								
10	Re-and/or cross-infection	Single use	3	2	1	6	Add the warning information to the product label and instruction for use	Product label Instruction for use	No	Yes
11	Pyrogenicity	N/A								
12	Inability to maintain hygienic safety	N/A								
13	Degradation	N/A								
D4. Environmental hazards and contributory factors										
1	Electromagnetic fields	N/A								
2	Inadequate supply of power or coolant	N/A								
3	Susceptibility to electromagnetic interference	N/A								
4	Emissions of electromagnetic interference	N/A								
5	Inadequate supply of power	N/A								
6	Inadequate supply of coolant	N/A								

Risk Analysis Jiangsu Dingjie Medical Equipment Co., Ltd.

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
7	Storage or operation outside prescribed environmental conditions	N/A								
8	Incompatibility with other devices	N/A								
9	Accidental mechanical damage	N/A								
10	Contamination due to waste products and /or device disposal	The product disposal may cause the environmental pollution.	2	2	1	4	The instruction for use illustrated that the products are not allowed to randomly discarded after use.	Instruction for use	No	Yes
D5. Hazards resulting from incorrect output of energy and substances										
1	Electricity	N/A								
2	Radiation	N/A								
3	Volume	N/A								
4	Pressure	N/A								
5	Supply of medical gases	N/A								
6	Supply of anaesthetic agents	N/A								
D6. Hazards related to the use of the device and contributory factors										
1	Inadequate labeling	The inadequate labeling may cause the product misused.	3	1	1	3	Use the adequate product label.	Product label	No	Yes
2	Inadequate operating instructions <ul style="list-style-type: none"> inadequate specification of accessories inadequate specification of pre-use checks over-complicated operating instructions inadequate specification of service and maintenance 	N/A								
3	Use by unskilled/untrained personnel	N/A								

Risk Analysis Jiangsu Dingjie Medical Equipment Co., Ltd.

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
4	Reasonably foreseeable misuse	N/A								
5	Insufficient warning of side effects	N/A								
6	Inadequate warning of hazards likely with re-use of single use devices	The inadequate labeling may cause the product misused.	3	1	1	3	Use the adequate product label.	Product label	No	Yes
7	Incorrect measurement and other metrological aspects	N/A								
8	Incompatibility with consumables/accessories/other devices	N/A								
9	Sharp edges or points	N/A								
C7. Inappropriate, inadequate or over-complicated user interface (man/machine communication)										
1	Mistakes and judgement errors	N/A								
2	Lapses and cognitive recall errors	N/A								
3	Slips and blunders (mental or physical)	N/A								
4	Violation or abbreviation of	N/A								

Risk Analysis Jiangsu Dingjie Medical Equipment Co., Ltd.

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
	instructions, procedures, etc.,									
5	Complex or confusing control system	N/A								
6	Ambiguous or unclear device state	N/A								
7	Ambiguous or unclear presentation of settings, measurements or other information	N/A								
8	Misrepresentation of results	N/A								
9	Insufficient visibility, audibility or tactility	N/A								
10	Poor mapping of controls to action, or of displayed information to actual state	N/A								
11	Controversial modes or mappings as compared to existing equipment	N/A								
D8. Hazards arising from functional failure, maintenance and ageing										
1	Erroneous data transfer	N/A								
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	N/A								

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
3	Inadequate maintenance	N/A								
4	Lack of adequate determination of end of device life	N/A								
5	Loss of electrical / mechanical integrity	N/A								
6	Inadequate packaging(contamination and /or deterioration of the device)	N/A								
7	Re-use and / or Improper re-use	The reuse of the product may cause accident	3	2	1	6	Mark the product with "single use" symbol on the product label	Product label	No	Yes
8	Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	N/A								

B2. Additional hazards to in vitro diagnostic medical devices

Risk Analysis Jiangsu Dingjie Medical Equipment Co., Ltd.

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
1	Batch inhomogeneity, batch-to-batch inconsistency	N/A								
2	Common interfering factors	N/A								
3	Carry-over effects	N/A								
4	Specimen identification errors	N/A								
5	Stability problems (in storage, in shipping, in use, after first opening of the container)	N/A								
6	Problems related to taking, preparation and stability of specimens	N/A								
7	Inadequate specification of prerequisites	N/A								
8	Inadequate test characteristics	N/A								

Risk Analysis Jiangsu Dingjie Medical Equipment Co., Ltd.

No.	Hard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				

Post-production experience										
	Post-production experience: Our products have high quality. Up to now, we did not receive any customer complain related product quality.									
	Review of risk management experience:									

Abbreviations used

RE	Risk Evaluation
S	Severity (9 –very severe, 0 –not severe)
O	Occurrence (9 – often, 0 –never)
D	Detection (9 –impossible to detect before risk occurs, 0 –will be certainly detected before risk occurs)
RL	Risk Level = Severity ×Occurrence ×Detection 1-9: neglectable risk, no further actions; 9-24:moderate: minimal risk, preventive action recommended; 25-48:moderate risk, preventive action required; >48: risk is usually not acceptable
RRM	Risk Reduction Measure
NH	New hazard generated (no/ yes - if yes, then number of new hazard indicated)
ALOR	Acceptable Level of Risk

7. Clinical information

The product is provided to domestic hospital, at the same time for other medical device manufacturer; the products have been well evaluated by the customers since being launched to the market. There has not been any customer complaint due to the product quality problems, nor product withdrawn by relevant state medical device supervision; the product quality is stable which has been well evaluated by the customer; the product market share has been enlarged gradually.

8. Concerning EC Representative Statement

关于确定欧洲代表的声明

本公司目前无产品销售到欧洲地区，也无确定欧洲代表，今后在产品出口欧洲之前确定好欧洲商及欧洲代表地址等，然后通知认证机构。

副总经理

职位

签名

2019.2.27

日期

Concerning European Representative Established within European Community

We have not sold products in Europe and not appointed European Representative established within European Community. We will nominate Distributor and Authorized Representative Established within European Community and inform Certification Body before our products were exported to Europe.

Vice-general Manager

Post

Zhang Zhaolin

signature

2019.2.27

date

9. EC declaration of conformity



EC declaration of conformity

Manufacturer: Jiangsu Dingjie Medical Equipment Co., Ltd.

Address of the manufacturer: No.219 Yanjiang Road, Changjiang Town, Rugao City, Nantong City,
Jiangsu Province, China

Name of the authorized representative of European Union:

Address of the authorized representative of European Union:

Product Name: Disposable Vinyl Examination Gloves

Product Type:

Disposable Vinyl Examination Gloves	9 inch, Powder free, Clear Color
	9 inch, Powdered, Clear Color
	9 inch, Powder free, Blue Color
	9 inch, Powdered, Blue Color
	9 inch, Powder free, Yellow Color
	9 inch, Powdered, Yellow Color

Product Classification: Class I

We hereby state that:

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives (93/42/EEC), and realize their expected uses. All CE files have been certified by the company and relevant notifying body, consequently their authenticity has been guaranteed.

Directive we are following:

European Union Committee Medical Device Directives MDD (93/42/EEC)

Standards we are implementing:

EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 455-1:2000, EN ISO 455-2:2009+A2:2013, EN ISO 455-3:2006, EN ISO 455-4:2009, EN 1041:2008

Company name: Jiangsu Dingjie Medical Equipment Co., Ltd.

General Manager:

Date: 2019/2/25

10. Test report

See Annex

11. Manual

(Ver 1.0)

Product Name: Disposable Vinyl Examination Gloves

Product Type: Powder-free

Product Model: Please see the follow list:



Model (Small, medium and large)	Nominal aperture (mm)	Minimum length(mm)	minimum thickness(mm)	maximum gauge (mm)
XS	≤ 80	230	0.08	0.22
S	80 ± 10	230		
M	95 ± 10	230		
		230		
L	110 ± 10	230		
		230		
XL	≥ 110	230		

Structure composition: this product is made of PVC

Scope of application: used to prevent cross infection between doctors and patients.

Performance index:

1. gloves, palms and fingers on single layer thickness of not less than 0.08 mm;
2. The gloves will not leak after being filled with 1000ml water for 2min.
3. The minimum breaking force before/after aging of gloves is 4.8n;
4. Minimum tensile elongation before/after aging of gloves: 350%;
5. The basic size of gloves is in accordance with the above table.

Instructions: when used for medical examination and health protection, it can effectively prevent cross-infection between doctors and patients. This product can be used in the department of stomatology, gynecology and other medical examinations, can not be used for surgery, can not contact strong acid, strong alkali

Matters needing attention:

6. for one-time use.
7. Gloves must be covered during transportation and placed in a dry place.
8. gloves should be stored in a cool, dry and ventilated warehouse (indoor temperature is below 30 °C, relative humidity 80% advisable). From the ground 20 mm shelves, should avoid to sunlight or ultraviolet composition strong artificial light of direct illuminate, no ozone generating device in warehouse.
9. the gloves shall not touch oil, acid, alkali and other substances during storage.

Validity: 2 years

Batch number:

Company legal person:



Jiangsu Dingjie Medical Equipment Co., Ltd.

No.219 Yanjiang Road, Changjiang Town, Rugao City, Nantong City, Jiangsu Province, China

