Technical Documentation

(File No. XTDC/CE03-01)
Version: A/0

Medical isolation gown

Specifications:
PP+PE, PP, SMS, PE

According to

Medical Device Regulation (EU) 2017/745
Annex II + Annex III + Article 19

	Name	Signature	Date
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Reviewed by	Du Jianmin		2020-05-06
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Document History Summary

No	Summary of Changes	Effective Date	Version
1	New established	2020-05-06	A/0

Table of Content

1 Brief Information

1.1 Introduction of the company

Contact information:

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1.2 Person responsible for regulatory compliance (PRRC)

Name: Wang Manzhen
Address: LIUKOU INDUSTRIAL PARK, XIANTAO CITY, HUBEI PROVINCE, CHINA
Position: Quality Manager
Diploma: College diploma
Work experience: many years in medical regulations including CE, FDA.

1.3 The authorized representative of European Union:

CMC Medical Devices & Drugs S.L.
Horacio Lengo № 18, CP 29006, Málaga, Spain

The agreement with the authorized representative of European Union, SEE:
Appendix 1 EC Authority Representative Agreement

1.4 Single Registration Number (RSN)

The company has registered in the Eudamed, the RSN is: .

2. List of Harmonized standard, Common specification, Guidance, other standard.

No.	Standard	Name of document
1	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
2	EN 1041:2008	Information supplied by the manufacturer of medical devices
3	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices.
4	EN 13795-2:2019	Surgical clothing and drapes - Requirements and test methods -Part 2 Clean air suits
5	ISO 9073-10:2003	Surgical drapes, gowns and clean air suits for patients, clinical staff and equipment - Part 4: Test method for linting in the dry state
6	EN ISO 22612:2005	Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration
7	ISO 22610:2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration
8	EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
9	ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing
10	ISO 10993-5:2009	Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity
11	ISO 10993-10:2010	Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction
12	ASTM D4169-2016	Standard practice for performance Testing of Shipping Containers and Systems
13	MDCG 2019-15	Guidance notes for manufacturers of class I medical devices
14	GB 19082-2009	Technical requirements for single-use protective clothing for medical use (China)

3. Product Descriptions

3.1 Intend use of device

The medical device is intended to be worn by healthcare providers or visitors to isolate themselves from patients, helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Single-use, Non-sterile.

Contraindications:

Users who is allergic to PP+PE, PP, SMS, PE materials.

Specifications: PP+PE, PP, SMS, PE

Validity of Medical isolation gown: 3 years.

GMDN code: 35492

UMDN code: 15037

3.2 Classification of the product

Medical isolation gown is an non-invasive device intended for short term use.

3.2.1 Product classification

According to Rule 1 defined in Annex VIII of MDR (EU) 2017/745:

- *"All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies."*

The device is is an non-invasive device intended for short term use, it is not sterile, without measuring function, or repeated use, therefore, the device is classified as Class I.

3.2.2 Application method

The product applies CE based on EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

3.3 Product principle and specifications

3.3.1 Product principle

Medical isolation gown is a garment made of natural and/or synthetic materials, intended to be worn by health care providers or visitors to isolate themselves from patients. The Medical isolation gown helps to protect the patient (e.g., burn patients) from the transfer of infectious agents carried by the health care provider or visitor; or it may help to protect the health care provider or visitor from a contagious agent which has infected the patient. This is a single-use garment.

The Medical isolation gown uses its materials characteristics as physical protection barrier to separate infectious substance so as to prevent contamination between patient and examiner.

As the definition of medical device in MDR (EU) 2017/745 Article 2(1) , the Medical isolation gown is a defined as a medical device.

3.3.2 Previous and similar generations of the device

3.3.2.1 Previous generation of the device

The Medical isolation gown is a standard devices designed and manufactured base on applied EN standards (EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018), there are no previous generations for the device.

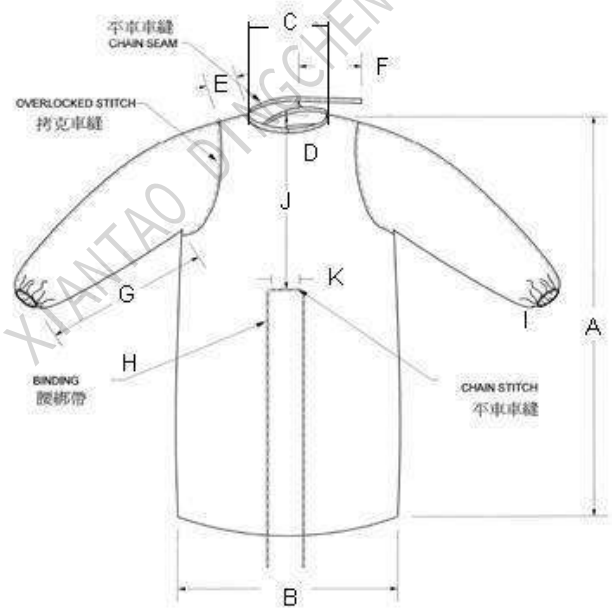
3.3.2.2 Similar device in the EU market

In the EU market, there are many Medical isolation gown brands, for all these Medical isolation gown, follows same EN standards (EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018) based on bench test.

3.3.2 Product specifications

Material	PP+PE, PP, SMS, PE		
Model	S	M	L
L x W（cm)	110x130	115x137	120x140
Sleeves (cm)	56	56	56
Cuff (cm)	16	16	16
Deviation (cm)	± 1.5	± 1.5	± 1.5

3.3.2.1 The structure of Medical isolation gown as follows:



3.3.2.2 Product pictures

3.3.3 Product UDI system

The UDI includes two parts: UDI-DI, UDI-PI.

All the specifications of the Medical isolation gown share same UDI-DI.

UDI	Number / Rules
UDI-DI	
UDI-PI	

3.4 Product performance

3.4.1 Technical performance

Item	Technical parameters
Appearance	The Medical isolation gown shall be clean, no foreign matters, no stain.
Dimensions	It shall comply the specification requirements.
Resistance to microbial penetration - Dry	≤ 2 Log_{10} (CFU)
Cleanliness - Mircrobial	≤ 2 Log_{10} (CFU/dm^2)
Cleanliness - Particulate matter	≤ 3,5 IPM
Linting	≤ 4,0 Log_{10} (lint count)
Bursting strength - Dry	≥ 40kPa
Tensile strength - Dry	≥ 20N
Moisture permeability (g/(m^2.24h)	≥ 2500
Impermeability (kPa)	≥1.67
Breaking force (N) Longitudinal direction Transverse direction	 ≥45 ≥45
Elongation at break Longitudinal direction	 ≥15

Transverse direction	≥15
Water staining (class)	≥3
Vertical combustion 1) After-flame time(s) Longitudinal direction Transverse direction 2) Continuous flame times (s) Longitudinal direction Transverse direction 3) Damaged length (mm) Longitudinal direction Transverse direction	 ≤10 ≤10 ≤15 ≤15 ≤200 ≤200

3.4.2 Storage conditions

The device should be stored in a cool, dry environment, the relative humidity under 80%, to avoid direct sunlight. Do not mix with anything toxic, harmful, smell, volatile.

3.5 Package of device

The Medical isolation gown has two packages, internal package and external package.

Internal package	PE bag, 10 pcs/bag
External package	Corrugated box, 100 pcs/carton

3.6 The suppliers information

No.	Components	Materials
1	Main body	PP+PE, PP, SMS, PE
2	Sleeves	PP+PE, PP, SMS, PE

4. General Safety and Performance Requirements

The product shall comply with GSPR defined in Annex I of MDR (EU) 2017/745.

SEE: Appendix 2 GSPR Checklist

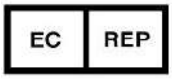
5. Label and Language Sample

5.1 All important aspects of labeling

5.1.1 Symbol for Medical device

5.1.2 Symbol for manufacturer

5.1.3 The name or trade name and address of the manufacturer, and the name and address of the authorized representative



5.1.4 Symbol for Unique Device Identifier (UDI)

5.1.5 Product name, type/size, specification, quantity

Symbol for "BATCH CODE"

- The relative size of the symbol and the size of the batch code are not specified.
- Synonyms for "batch code" are "lot number", "batch number".

Example of use of symbol for "BATCH CODE"

5.1.6 Expiry date

Symbol for "USE BY"

- The date shall be expressed as four digits for the year and two digits for the month
- The relative sizes of the symbol and the date are not specified.
- This symbol shall be accompanied by a date to indicate that the device should not be used after the end of the year, month or day shown.

Examples of use of symbol for "USE BY"

5.1.7 An indication that the device is for single use

Symbol for "DO NOT REUSE", "single use", "Use only once".

5.1.8 Date of manufacture

Symbol for "DATE OF MANUFACTURE"

- The relative sizes of the symbol and the date are not specified.
- This symbol can be filled or unfilled. If filled, the date of manufacture as well as the name and address of the manufacturer can be combined in one symbol

Example of use of symbol for “MANUFACTURER” combined with “DATE OF MANUFACTURE”

5.1.9 Catalogue number

Symbol for "CATALOGUE NUMBER"

-The relative size of the symbol and the size of the catalogue number are not specified.

-Synonyms for "catalogue number" are "reference number", "re-order number".

Examples of use of symbol for "CATALOGUE NUMBER"

REF ABC123

5.1.10 Caution

Symbol for "CAUTION"

- This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol “Caution” is still sometimes used to have the meaning of “Attention, see instructions for use”

5.1.11 Keep dry

Symbol for “KEEP DRY”

5.1.12 CE mark

- The diameter of the drawing ≥5mm.
- At the lower right corner of the CE mark, label the registration number of the notified body.
- CE-mark should be distinct, clear and wear well.

5.2. The label-used language must be in accordance with the EC requirements and its accuracy is to be assured.

5.2.1 Special requirements

5.2.1.1 The Model face, symbol, size and location on label are not prescribed. But the handwriting should be clear, obvious and durable.

5.2.1.2 If there is a special requirement on label from customers，the company should design manufacture label in accordance with requirements of customers or mark from customers.

5.2.1.3 Language on label should be up to requirements of European countries and ensure the accuracy.

5.2.2 Normative Reference

- MDR (EU) 2017/745
- EN ISO 15223-1:2016
- EN 1041: 2008

5.3. Label and Instruction for Use

The instruction for use of the Medical isolation gown, please see the follows:

Labeling and package	Label-XTDC03
Instruction for use	IFU-XTDC03

6 Risk analysis plan

6.1 Foreword

This plan is to describe the risk control carried on the Medical isolation gown manufactured by our company. All potential hazards and potential cause of each hazard have been determined in this report. Evaluations have been made on possible severity level may led by each hazard and probability of occurrence of each hazard. For unacceptable risks, necessary measures must be taken, and also evaluate the residual risk level after taking relevant measures.

By taking proper measures to reduce the risks which may lead to various kinds of potential hazards to the acceptable level, and also to reduce the total amount of every kind of hazards to the acceptable level.

6.2 Purpose

Aim of this risk control is to carry out determination on all risks that may be led by the Medical isolation gown that have been put into production in our company, also to stipulate the necessary relative measures, in order to keep the risk level within an acceptable level. By taking risk control the company may take relative measures of continuously improving quality of the products, to meet customer stipulated or potential requirements constantly.

6.3 Application.

This risk analysis is applied to Medical isolation gown produced by the company.

6.4 Documents reference

6.4.1 Standards

See sec.2 of the CE technical file.

6.4.2 Production specification

See sec.3 of the CE technical file.

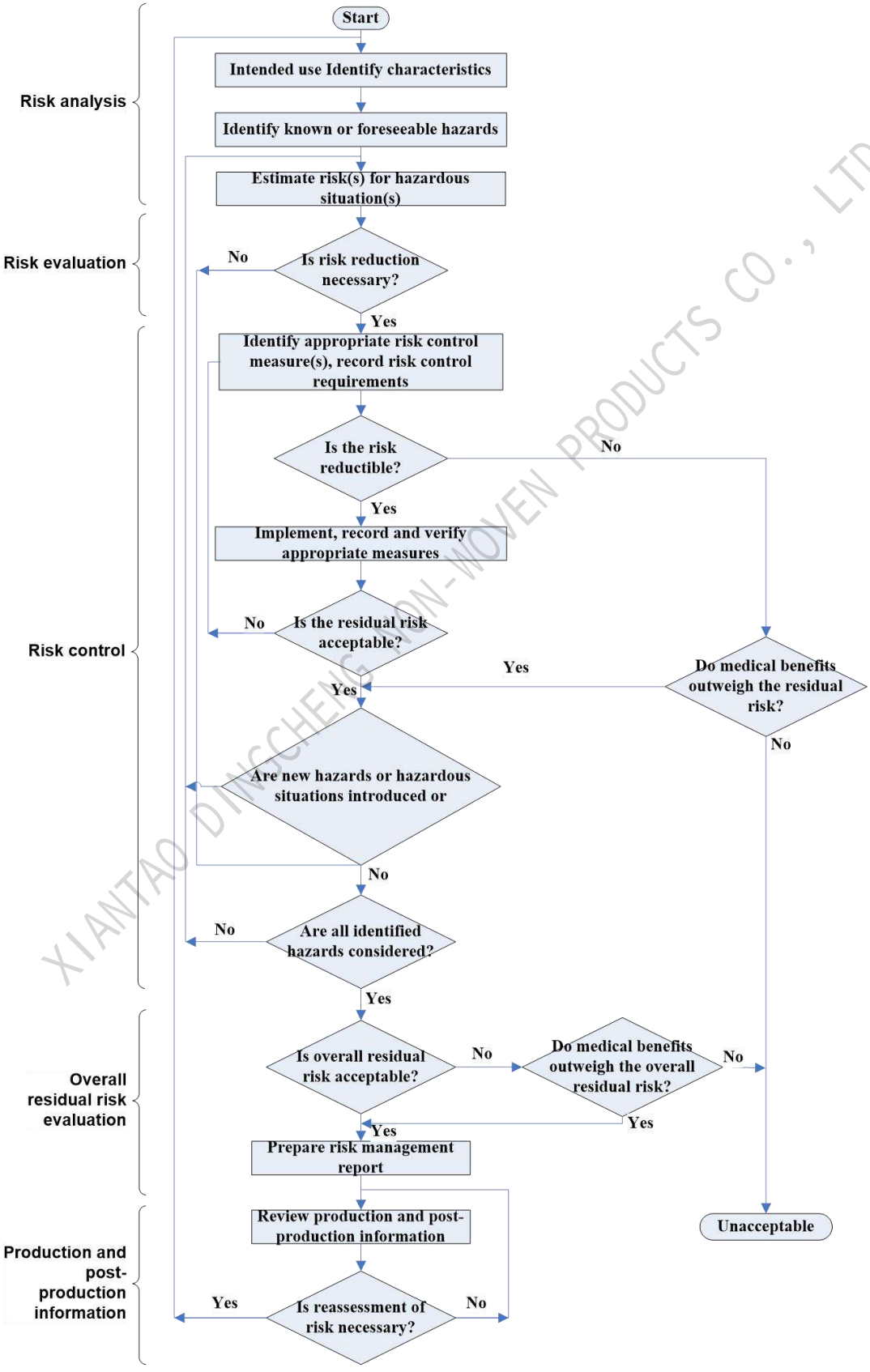
6.5 Members of the risk control group

Name	Title	Responsibility	Authority
Chen Peng	General manager	General control of Risk management	Approve the risk management plan and risk management report.
Cheng Qin	Management	Risk management for	Review and implement the

	Representative	product realization phase	risk management plan
Wang Manzhen	Tech & Quality manager	Risk management for product realization phase	Review and implement the risk management plan
Du Jianmin	Production & Purchasing manager	Risk management for product realization phase	Review and implement the risk management plan
Li Dingshan	Marketing manager	Risk management for post-marketing surveillance phase	Review and implement the risk management plan
Wang Manzhen	Tech & Quality manager	Prepare the Risk analysis report XTDC/CE03-01-07	/

6.6 Risk management process

Overview of the steps in the risk management process see the following flowchart:



6.7. Implementation of risk control process

6.7.1 Step1: Determination on known and foreseeable hazards

The hazard will be marked with “H……” in risk control form. (see the Risk analysis report XTDC/CE03-01-07)

Information resources: the following information can be regarded as potential hazard list

- ·Available Risk analysis report XTDC/CE03-01-07 on homologous product
- ·Investigations on developer of the product
- ·Determinations made by medical experts
- ·Analysis medical devices report from foreign authorities
- ·Site documents, complains and accident records gained from homologous products which have been put into use.

6.7.1.1 Estimation on severity level of each hazard

Severity level of each hazard must be estimated and semi-quantitative judged (in the form of serious level) by the medical expert

Severity level	Code	Description
Negligible	S1	No influence on use
Minor	S2	Inconvenience or temporary discomfort
Serious	S3	Results in temporary injury or impairment not requiring professional medical intervention
Critical	S4	Results in temporary injury requiring professional medical intervention
Catastrophic	S5	Permanent or serious injuries (e.g. serious infection)

6.7.1.2 Judgment of potential causes of each hazard

Members of the group shall at first find the potential causes directly base on their professional knowledge.

The founded hazard causes must be recorded in “Cause” column of risk control report, and mark with “C…”. (see the Risk analysis report XTDC/CE03-01-07)

6.7.1.3 Estimation on probability of occurrence of each cause

Occurrence probability of each potential cause must be estimated. In addition, the relative information resources are:

- Using experience of equivalent products (e.g. service statistic data)
- Customer complain
- Investigation on service life of self product

- Expert judgment

Such estimation carried out by relative personnel can be divided into following 5 categories:

Level	Code	Probability of occurrence
Improbable	P1	$<10^{-7}$
Remote	P2	10^{-6}~10^{-7}
Occasional	P3	10^{-5}~10^{-6}
Probable	P4	10^{-4}~10^{-5}
Frequent	P5	10^{-3}~10^{-4}

6.7.2 Step2: Risk estimation (before taking control measures)

Two risk factors were concluded in first hazard/cause item: hazard severity level and occurrence probability, relative risk. Three “risk area” can be defined according to advise of ENISO14971:2012.

1. Not acceptable area: U
2. Wide acceptable area: A

6.7.3 Step3: Risk evaluation

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)	U	U	U	U	U
Probable (P4)	A	U	U	U	U
Occasional (P3)	A	A	A	U	U
Remote (P2)	A	A	A	A	U
Improbable (P1)	A	A	A	A	A

U: Unacceptable risk

A: Insignificant risk

All risks estimated for each hazard/cause must be recorded in column of risk control form in the form of risk range (U, A) categories, and noted separately whether control measures are available.

6.7.4 Step4: Taking risk control measures

If no control measures are available for estimated risks, it is unacceptable, then control measures must be taken for each hazard cause. If several control measures were designed at the same time, then the effect will be the result when all relative control measures are taken.

All the measures must be recorded in the column “relative measures” of risk control form, and marked with “M….”. (see the Risk analysis report XTDC/CE03-01-07)

6.7.5 Step5: Evaluation on residual risks

The severity level or occurrence probability will be decreased or both of the stated after taking control measures. Sometime it cannot be quantificationally determined that in which level a group of relative control measures can decrease the risk factors (severity level or occurrence rate). The evaluation on residual risks is the summing-up of analysis of the group members based on their individual professional knowledge.

All changing of each category must be recorded in the column “residual risk” of risk control form. (see the Risk analysis report XTDC/CE03-01-07)

The residual risk of each hazard/cause may base on the determined risk area (U, A) stipulated in the previous chapter.

6.7.6 Step6: Risk/benefit analysis

It shall conclude for risk/benefit analysis after implement all control methods.

If A range is the result of risk decreasing, then an explanation must be made on why the further risk decreasing is unpractical.

6.7.7 Step7: Result of risk control

As showing in the risk control form (see the Risk analysis report XTDC/CE03-01-07), the residual risks of each hazard/cause shall be reduced to acceptable, total amount of residual individual risk shall also be regarded as acceptable.

6.7.8 Step8 Production and post-production information

Collect and review information about the medical device or similar devices in the production and post-production phases.

6.8 Conclusion on risk control

As displayed in Risk analysis report XTDC/CE03-01-07 (see XTDC/CE03-01-07), there have carried out more detailed risk analysis and evaluation on all items that may occur hazard led by the Medical isolation gown through the above, and think all risks are under

control and acceptable, also been verified by long term clinic use, the occurrence probability is extremely low, safety of the medical device has been adequately stipulated, summing up all the above, we think the risks are all under control and be acceptable. When new documents and data are used, the new round of risk analysis shall be carried out, for example, along with time passing, the risk may change and production process and product structure may be change accordingly. New risk may occurs or to be determined for the first time.

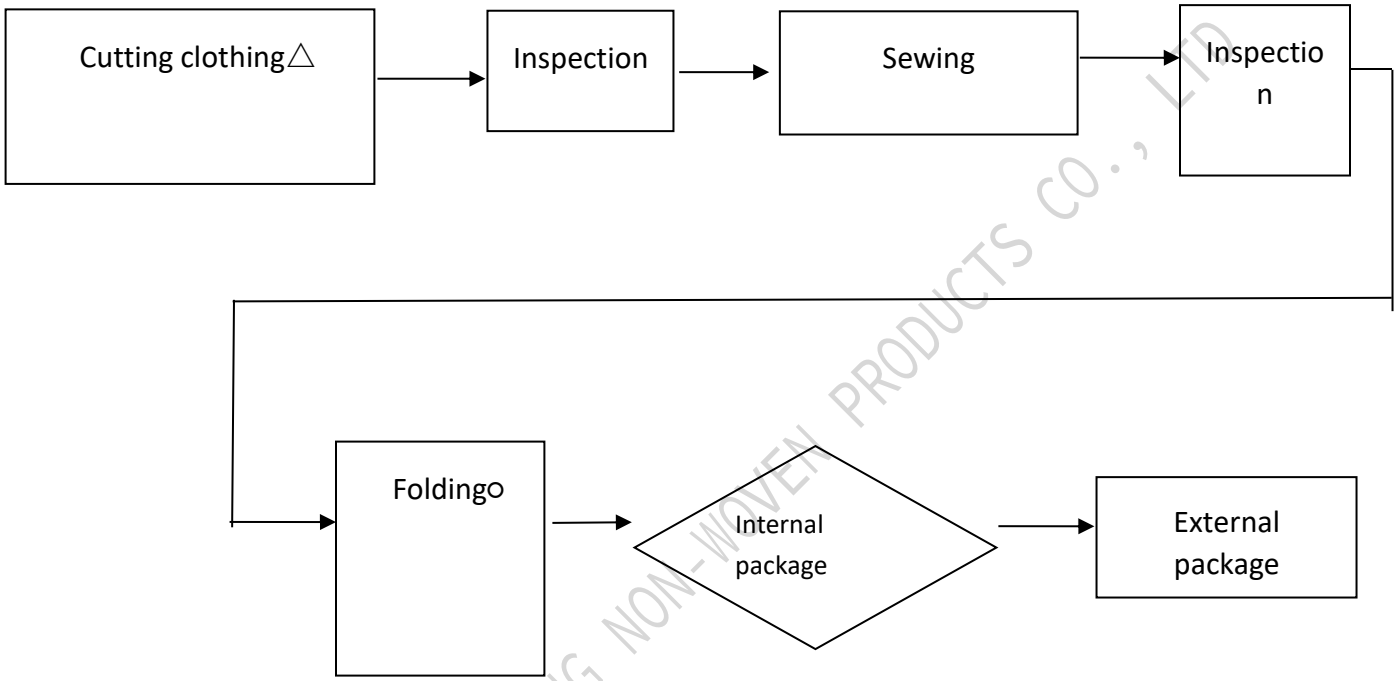
6.9 Appendix

Appendix 4 Risk analysis report XTDC/CE03-01-07

7. Production and quality control

7.1. Production flow

See the production flowchart.



7.2 Quality control

The company has conducted EN ISO13485:2016 QMS, and all production processes are on control under this QMS and MDR (EU) 2017/745.

7.2.1 Process control

Mainly, production environment, production equipment and production process are controlled, the control procedure of which is given in *Manufacturing and Service Process Control Procedure*

7.2.2 Environmental control

The device is manufactured in the production environment is given in *Production Equipment and Working Environment Control Procedure.*

7.2.3 Control of production equipment

Control of production equipment is given in *Production Equipment and Working Environment Control Procedure.*

7.2.4 Control of design and development

Control of design and development is given in *Design and Development Control Procedure*

7.2.5 Control of production process

a) Control of materials: control procedure for materials is given in *Purchasing Control Procedure;* quality control of materials is given in *Manufacturing and Product Testing and Inspection Control Procedure.*

b) Process control: process control is given in *Manufacturing and Product Testing and Inspection Control Procedure.*

c) Control of special processes: control of processes, including welding, is given in *Manufacturing and Product Testing and Inspection Control Procedure.*

7.2.6 Control of unaccepted products

Control procedure for unaccepted products is given in *Non-Conforming Control Procedure.*

7.2.7 Control of product identification and traceability

Control of product identification and traceability is given in *Identification and Traceability Control Procedure.*

7.2.8 Identification of raw materials

Identification of raw materials begins from the moment the materials are brought into the plant (put in storage); all raw materials are stored upon passing IQC procedure, with article card account and status marking, storage sheet, and stock requisition sheet. Expressions of the raw materials (production lot number, incoming lot number) enter the production flow along with articles.

7.2.9 Identification of finished products

Test report of finished products are the ‘acceptable’ identification of finished products; the test report is only issued when the finished products are tested accepted lot by Lot.

7.2.10 Commodity identification

Accepted products become commodities when sold, and their flow direction, production lot number, specification and quantity are all recorded in the sales account, which is the identification for internal trace.

7.2.11 All identifications are the only record.

7.2.12 Trace

a. Back trace

The process number can be traced by the product certification, and by the process number, date of the whole production process, operator, inspection status and quantity, as well as inspector and materials number can be traced; by the date on the identification card, working environment can be traced in the environment records of the day; by the inspection status and quantity, the acceptance status of half-finished products can be traced; by the stock requisition sheet, the production lot number and acceptance status of raw materials can be traced; and by the operator and the inspector, the persons in charge

can be traced.

b. Forward trace

If batches of adverse incidents are reported, the commodities can be recalled according to the sales account, which also facilitates making a public announcement where the commodities are distributed.

7.2.13 Control over the final release of products

Final release of products is given in *Manufacturing and Product Testing and Inspection Control Procedure.*

7.2.14 Preventive control during flow

It is given in *Vigliance System and Advise Notice Issuing Control Procedure* and *Corrective and Preventive Action Control Procedure.*

7.3 Design and Manufacturing Control

7.3.1 Design of device

The company implement the design of Medical isolation gown based on ISO 13485 section 7.3, and applied other regulations and standards.

The design flow follows Design plan, Design input, Design output, Design review, Design verification, Design validation, Design transfer defined in ISO 13485 section 7.3. These design records as follows:

Design stages	Design records
Design plan	1) R&D advice; 2) Product project application; 3) R&D task; 4) R&D plan); 5) R&D plan review report;
Design input	1) Design input sheet; 2) Design input accessories; 3) Risk management plan;
Design output and review	1) Design output sheet; 2) R&D output review report; 3) Risk management report;
Design verification and validation	1) Trial production report; 2) Process validation plan; 3) R&D verification report; 4) R&D validation report ;
Design transfer	R&D transfer report.

7.3.2 Manufacturing control
The manufacturing control of Medical isolation gown is implemented based on ISO 13485 and applied other regulations and standards.
The manufacturing control documents see:
Appendix 5 Design and Manufacturing Control

8. Pre-clinical Assessment

8.1. Introduction

The Medical isolation gown, must be made sure that it comply with the provisions of standards EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018 and other relative standards before product clinical use, thus ensuring CE products in conformity with their intended use, and also ensuring their safety and reliability.
All the following appearance, use function, bio-compatibility test and sterile test, are conducted for purpose of pre-clinical assessment.

8.2. Product performance assessment

The Medical isolation gown shall comply with EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018 and the company standard requirements, as defined in sec.3
The product performance test, SEE: Appendix 6 Product Test Reports

8.2 Symbols & Labeling, Instruction for use

8.2.1 Requirements: the symbol and label, Instruction for use shall comply with EN ISO 15223-1:2016, EN1041:2008.
8.2.2 Test method: visual inspection
8.2.3 Result: meet the requirement, SEE: Appendix 3 Instruction for use, Labeling

8.3 Bio-compatibility evaluation

8.3.1 Purpose of Biological Evaluation
In order to ensure the product to comply with MDR (EU) 2017/745 and protect the human against the potential biological risk generated by the use of this product, the Biological Evaluation is conducted for the product marked CE for guaranteeing the safety of product in the use.

8.3.2. Process of Biological Evaluation of Medical Device
Biological Evaluation of Medical Device is conducted in accordance with the flow chart stated in ISO 10993-1:2018 “Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within A Risk Management Process” (The dotted line marked in the chart

below gives the process of Biological Evaluation of this product) .

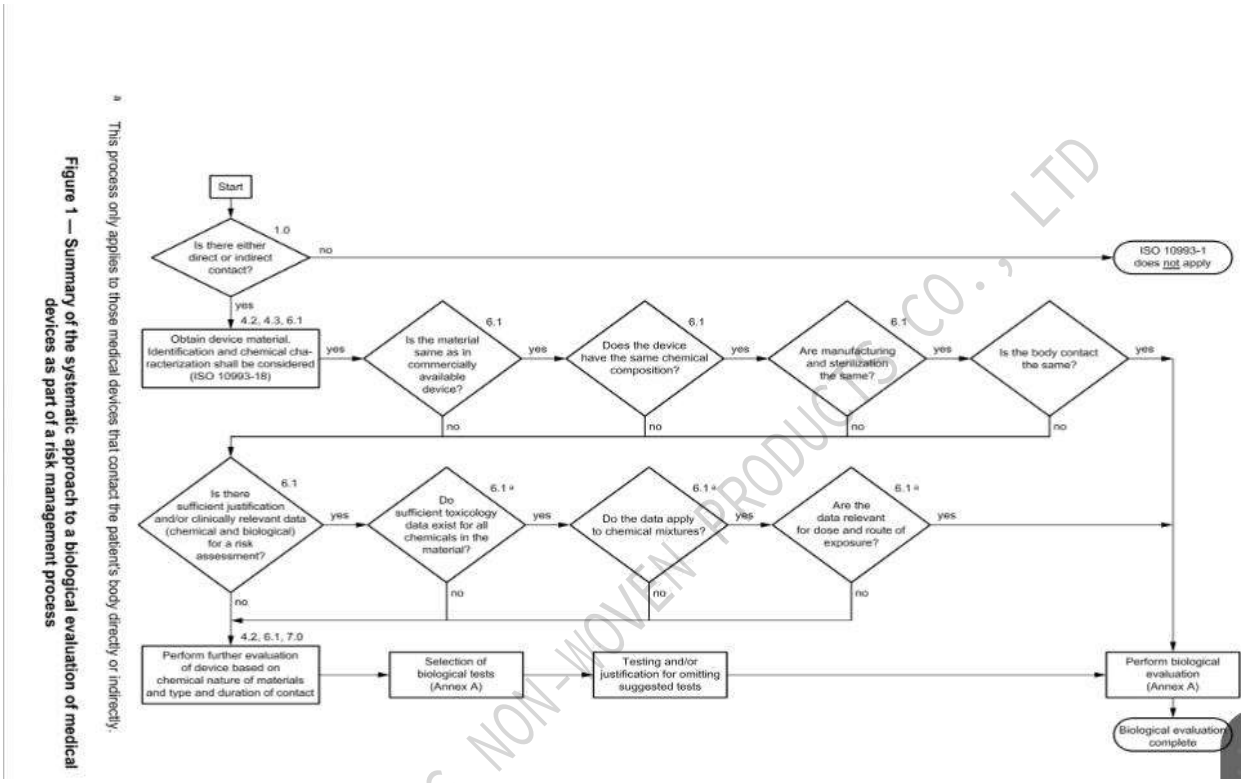


Figure 1 — Summary of the systematic approach to a biological evaluation of medical devices as part of a risk management process

a This process only applies to those medical devices that contact the patient's body directly or indirectly.

Description of Route Through by the Product in Flow Chart:

1) Is there either direct or indirect contact?

Yes.

Intended use of product: The Medical isolation gown is a disposable device intended for medical purposes that is worn on the examiner's hand or finger(s) to prevent contamination between patient and examiner.

The device will directly contact with users surface skin.

2) Obtain device material, identification and chemical characterization shall be considered.

The material characterization as follows:

Table 8.1 Material characterization of device

Parts and components	Materials	Nature of body contact	Contact duration

Clothing	PP+PE, PP, SMS, PE,	Direct skin surface contacting with users	Prolonged exposure (>1 hour, but <30 days)

3) Is the material same as in commercially available device?
No. Though the materials are common used medical materials, it is difficult to ensure that these materials are same as in commercially available device

4) Is there sufficient justification and/or clinically relevant data (chemical and biological) for a risk assessment?
No. There are not sufficient justification.

According to above evaluation, the device shall implement bio-compatibility tests.
According to Annex A of EN ISO 10993-1:2018, it shall conduct vitro cytotoxicity, stimulation, allergic reaction which correspondingly to ISO 10993-10:2010.

8.3.3 Inspection items:
Skin irritation test
a) In this test a proper model is used to measure the implied stimulation effect of a device, material and/or its diffusate on the implanted part of subcutaneous tissue. This stimulation test must be carried out by considering the practical means of the use or contact(skin. etc) and duration period, and accommodating them to the test.
b) According to the above method, inject a certain quantity of CE product diffusate into the rabbit skin , observe the skin reaction and evaluate the tested material stimulation to the tissue.
3) Skin sensitization test
a) In this test a proper model is used to determine the implied allergy by contact.
b) By means of a certain quantity of collecting needle dffusate in touch with guinea-pig skin, a determination can be made to know if the tested article can cause a contact-related skin allergic reaction.

8.3.4 Test methods:
The device manufactured by our company have sampled for testing and all passed the test on ISO 10993-5:2009, ISO 10993-10:2010.
According to test results, all pass the test.
SEE: Appendix 6 Product Test Reports

8.4 Risk Analysis
In the Risk analysis report XTDC/CE03-01-07, an analysis has been made on the

possible risk of the product from their material to production process, and the effective actions for controlling the risk have been taken to reduce it to an acceptable extent. The report shows that the application value of the CE product is much larger than their risk, i.e. the residual risks is acceptable when weight against the intended benefits of the device.

8.5 Conclusions

According to above analysis, and the test reports. It is defined that the Medical isolation gown is qualified if all of above items comply with requirements, and unqualified and cannot be used in production if any one of above items is not passed. As for CE product, they can be put to market only when the products can go through the above terms.

9. Usability evaluation

The company compile the usability report according to EN 62366-1:2015+AC:2015.

SEE Appendix 8 Usability Validation Study

10. Benefit-Risk Analysis

SEE: Appendix 9 Benefit-Risk analysis report XTDC/CE03-01-07

11. Clinical Evaluation

The company compile the clinical evaluation report according to MDR (EU) 2017/745.

The company update the CER yearly.

SEE: Appendix 7 Clinical Evaluation Report

12. Declaration of Conformity

SEE: Appendix 10 EU Declaration of Conformity

Product name:	Medical isolation gown
Specifications:	PP+PE, PP, SMS, PE
Legal Manufacturer:	XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD LIUKOU INDUSTRIAL PARK, XIANTAO CITY, HUBEI PROVINCE, CHINA

Accessories: N.A

2020-05-06	Wang Manzhen	
Date	*Name Preparer*	*Signature Preparer*
2020-05-06	Du Jianmin	
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2020-05-06	Cheng Qin	
Date	*Name Approved*	*Signature Approved*

Checklist according to annex I of the Medical Device Regulation (MDR) 按 医 疗 器 械 法 规 （MDR） 附 录 一 的 基 本 要 求 检 查 表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
I.	**CHAPTER 1 General Requirements** **第一章 通 用 要 求**				
1.	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall 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, taking into account the generally acknowledged state of the art. 器械应具备制造商预期的性能，并确保其设计和结构在正常使用条件下适用于其预期用途。器械应安全有效，且不得对患者的临床症状或安全或者使用者或其他人员（如适用）的安全和健康造成损害，在最大限度保护健康和安全的同时，器械使用的可接受风险与其对患者的益处相比，应在可接受范围内，并应考虑到符合现有认知水平。	A	EN 13795-2:2019 ISO 9073-10:2003 EN ISO 22612:2005 ISO 22610:2018 EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02) Clinical evaluation report (XTDC/CE03-01-03) Usability Evaluation (XTDC/CE03-01-04) Benefit-Risk analysis report XTDC/CE03-01-07 (XTDC/CE03-01-05) Product test reports (Appendix 6)	Quality Dept.
2.	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio. 本附录中尽可能降低风险的要求指尽可能降低风险的同时不会对收益风险比产生不利影响。	A	EN ISO 14971:2012	Risk analysis report XTDC/CE03-01-07 Benefit-Risk analysis report XTDC/CE03-01-07 (XTDC/CE03-01-05)	Quality Dept.
3.	Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying	A	EN ISO 14971:2012	Risk analysis report XTDC/CE03-01-07 Benefit-Risk analysis report XTDC/CE03-01-07 (XTDC/CE03-01-05)	Quality Dept.

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	out risk management manufacturers shall: (a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4. 制造商应建立、实施、记录和维护风险管理体系。 风险管理应理解为在器械整个生命周期中为连续迭代过程，需定期进行系统更新。进行风险管理制造商需做到： (a) 制定并记录各器械的风险管理计划； (b) 识别和分析与各器械相关的已知和可预见的危害； (c) 估计和评价在预期使用时及在可合理预见的使用不当时产生的相关风险；				

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	(d) 根据第 4 节的要求消除或控制(c)点所述的这些风险； (e) 评估生产阶段，特别是上市后监管体系的信息、危害及其发生频率、评估其相关风险及总体风险、风险利益比和风险可接受性。 根据(e)点所述信息影响的评估，必要时根据第 4 节的要求修改控制措施。				
4.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (a) eliminate or reduce risks as far as possible through safe design and manufacture; (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks. 制造商就器械的设计和制造所采取的风险控制措施应符合安全原则，并考虑到现有的技术水平。为降低风险，制造商应对风险进行管理，使各危害相关的剩余风险及总剩余风险控制在可	A	ISO 13485:2016 EN 13795-2:2019 ISO 9073-10:2003 EN ISO 22612:2005 ISO 22610:2018 EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02) Clinical evaluation report (XTDC/CE03-01-03) Usability Evaluation (XTDC/CE03-01-04) Benefit-Risk analysis report XTDC/CE03-01-07 (XTDC/CE03-01-05) Product test reports (Appendix 6)	Quality Dept.

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	接受范围内。在选择最合适的解决方案时，制造商应依据下述优先级原则： (a) 通过安全的设计和制造尽可能消除或降低风险； (b) 如适合，采取适当保护措施，关于无法消除的风险，包含必要时的报警；且 (c) 提供安全信息（警戒/预防措施/禁忌），并在适当情况下向使用者提供培训。 制造商应将剩余风险告知使用者。				
5.	In eliminating or reducing risks related to use error, the manufacturer shall: (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 在消除或减少使用不当相关风险时，制造商应： (a) 尽量降低因器械人体工程学特点及其预期使用环境所造成的风险（针对患者安全而设计），以及 (b) 针对技术知识、经验、教育、培训和使用环境，以及预期使用者医疗及身体条件（如适用）的注意事项（针对非专业、专业、残疾或其他使用者而设计）。	A	EN ISO 14971:2012 EN 62366-1:2015+AC:2015	Risk analysis report XTDC/CE03-01-07 Usability Evaluation (XTDC/CE03-01-04) Benefit-Risk analysis report XTDC/CE03-01-07 (XTDC/CE03-01-05)	Quality Dept.

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6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user 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 and has been properly maintained in accordance with the manufacturer's instructions. 如器械在正常使用环境中使用并根据制造商的指示进行适当维护保养，在制造商声称的使用期限内器械的特性和性能不得对患者、使用者或其他人员（如适用）的健康或安全造成损害。	A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.
7.	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer. 器械的设计、制造和包装应确保在根据制造商提供的说明和信息进行运输和储存期间（如温度和湿度的波动），不会对器械在预期使用期间的特性和性能造成不利影响。	A	EN 13795-2:2019 ISO 9073-10:2003 EN ISO 22612:2005 ISO 22610:2018 ASTM D6124-06 (2017)	Product test reports (Appendix 6)	Quality Dept.
8.	All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. 与正常使用条件下器械预期性能对患者和/或使用者产生的潜在益处相比，所有已知和可预见的风险及任何不良影响应	A	EN ISO 14971:2012	Risk analysis report XTDC/CE03-01-07 Benefit-Risk analysis report XTDC/CE03-01-07 (XTDC/CE03-01-05)	Quality Dept.

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	最小化并控制在可接受范围内。				
9.	For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons. 对于在附录 XVI 中所列出的，制造商未声称用于医疗目的之器械，应充分了解在第 1 节和第 8 节规定的通用安全要求，即在预期条件下出于预期目的而使用器械时，器械不得出现任何风险，或出现不超过与产品使用相关的最大可接受风险，这符合高水平保障人员安全和健康原则一致。	N.A	The device does not apply for Annex XVI of MDR, the device intended use classification is clear.		
II.	**CHAPER II REQUIREMENTS REGARDING DESIGN AND MANUFACTURE** **设计和生产的要求**				
10.	**Chemical, physical and biological properties 化学、物理和生物学特性**				
10.1	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: 器械的设计和生产应当能确保符合第 I 章中所述的特性和性能要求。特别注意：	A	EN 13795-3:2006, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010,	Product test reports (Appendix 6)	Quality Dept.
	(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;	A	EN 13795-3:2006, ISO 10993-1:2018, ISO 10993-5:2009,	Product test reports (Appendix 6)	Quality Dept.

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	使用材料和物质的选择，特别是毒性和易燃性（如适用）		ISO 10993-10:2010,		
	(b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion; 所使用材料和物质与生物组织，细胞及体液间的相容性，及考虑到器械使用目的及相关的吸收、分布、新陈代谢和排泄；	A	EN 13795-3:2006, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010,	Product test reports (Appendix 6)	Quality Dept.
	(c) the compatibility between the different parts of a device which consists of more than one implantable part; 器械不同部件之间的兼容性，该器械由多个可植入部件组成；	N.A	The device is used independently and no connected parts		
	(d) the impact of processes on material properties; 过程对材料性能的影响；	A	EN 13795-3:2006, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010,	Product test reports (Appendix 6)	Quality Dept.
	(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; 如适用，生物物理学或建模研究结果有效性已事先获得证实；	A	EN 13795-3:2006, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010,	Product test reports (Appendix 6)	Quality Dept.
	(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; 所使用材料的机械性能，在适当情况下反映诸如强度、延展性、抗断裂性、耐磨性和耐疲劳强度等问题；	A	EN 13795-2:2019 ISO 9073-10:2003 EN ISO 22612:2005 ISO 22610:2018	Product test reports (Appendix 6)	Quality Dept.

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	(g) surface properties; and 表面特性；	A	EN 13795-2:2019, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010,	Product test reports (Appendix 6)	Quality Dept.
	(h) the confirmation that the device meets any defined chemical and/or physical specifications. 确认该器械满足任何确定的化学和/或物理要求。	A	EN 13795-2:2019 ISO 9073-10:2003 EN ISO 22612:2005 ISO 22610:2018	Product test reports (Appendix 6)	Quality Dept.
10.2	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure. 器械的设计、生产和包装应尽可能降低污染物和残留物对患者造成的风险，同时考虑到器械预期用途以及参与器械运输、储存和使用的人员。应当特别注意暴露于这些污染物和残留物的组织以及暴露时间与频率。	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.
10.3	Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.

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	use. 器械的设计和生产应以能使其可安全地与材料和物质（包括气体）一起使用，且在预期使用时，这些材料和物质会与器械接触；若器械预期用于管理医疗产品，根据管理这些医疗产品的条款和限制，则其设计和制造应使其能够与相关的医疗产品兼容，并应可根据其相应的指示和预期用途维护医疗产品和器械的性能。				
10.4	Substances 物质				
10.4.1	Design and manufacture of devices 器械的设计和生产 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that: 器械的设计和制造应尽可能降低由物质或颗粒（包括磨屑、降解产物和加工残留物）造成的风险，而此类物质或颗粒可能由器械产生。 器械或其部件或其使用的材料：	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.
	— are invasive and come into direct contact with the human body, 具有侵入性，并与人体直接接触，或	N.A	The device is non-invasive device		
	— (re)administer medicines, body liquids or other substances, including gases, to/from the body, or	N.A	The device doesn't administer medicines, body liquids or other substances		

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	（重新）为人体输送药物、体液或其他物质（包括气体），或 — transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, 运输或储存待（重新）为人体输送药物、体液或物质（包括气体），				
	shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: 在根据第 10.4.2 节进行合理性论证时，应仅包含浓度高于 0.1%重量比的以下物质： (a) substances which are carcinogenic, mutagenic or toxic to reproduction (‘CMR’), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or 1A 或 1B 类有致癌、致突变或生育毒性('CMR')的物质，依据欧洲议会和理事会第 1272/2008 号法规附录 VI 第 3 部分判断，或	N.A	The device does not includes these substances		
	(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3),	N.A	The device does not includes these substances		

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	in accordance with the criteria that are relevant to human health amongst the criteria established therein. 有科学证据证明可能对人类健康造成严重影响的具有内分泌干扰性质的物质，根据欧洲议会和理事会第 1907/2006 号法规第 59 条规定程序识别，或者委员会根据欧洲议会和理事会第 528/2012 号法规）第 5（3）条第一段通过授权法案后，根据本法规规定之与人类健康相关准则识别。				
10.4.2	Justification regarding the presence of CMR and/or endocrine-disrupting substances. The justification for the presence of such substances shall be based upon: (a) an analysis and estimation of potential patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such	N.A	The device does not includes these substances		

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	substances and/or materials; and (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4. 关于存在 CMR 和/或内分泌干扰物的理由，存在此类物质的理由应基于： (a) 对潜在患者或使用者暴露于该物质下情况进行分析和判断； (b) 对可能的替代物质、材料或设计进行的分析，（在可用时）包括有关独立研究、同等评审研究、相关科学委员会的科学意见等信息，以及对这些替代品可用性的分析； (c) 论证可能的物质和/或材料替代品（如有）或设计变更（如可行）不适用于维护产品功能、性能和利益-风险比的原因；包括要考虑这些器械的预期用途是否包括儿童治疗，或孕妇或哺乳妇女治疗，或对其他特别容易受到此类物质和/或材料影响的患者群体的治疗； (d) 如适用和可用时，基于根据第 10.4.3 节和 10.4.4.节制定的最新相关的科学委员会指南。				
10.4.3	Guidelines on phthalates For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into	N.A	The device does not includes these substances		

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	account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated. 邻苯二甲酸酯使用指南 为达到该附录第10.4节的目的，委员会应尽快并于2018年5月26日向相关科学委员会提供任务以制定指南，且该指南应在2020年5月26日前编制好。委员会的任务至少应包含对邻苯二甲酸酯存在的利益风险评估，其中邻苯二甲酸酯属于第10.4.1节要点（a）和（b）中所所述物质组中的任何一组。利益风险评估应考虑器械、可用替代物质和替代材料、设计和/或药物治疗使用的预期目的和环境。虽然根据最新科学证据认为是适当的，但应至少每五年更新一次该指南。				
10.4.4	Guidelines on other CMR and endocrine-disrupting substances Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate. 其它 CMR 和内分泌干扰物质的指南 随后，委员会应委任相关科学委员会按照第107.4.3中所述的要求，也为第10.4.1节要点（a）和（b）中所所述的其他物质制定指南。				

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10.4.5	Labelling Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use. 标签 按照第10.4.1节所述的要求，若此中所使用的器械、其部件或材料，包含第10.4.1节中所述的浓度高于0.1%重量比的物质，则应在器械本身和/或各单元的包装上或，（适当时）在销售包装上把此类物质清单标记清楚。若此类器械的预期用途，包括儿童治疗，或孕妇或哺乳妇女治疗，或对视为特别易受到此类物质和/或材料影响的其他患者群体的治疗，则关于这些患者群体的残余风险、（如适用）预防措施信息，均应在使用说	N.A	The device does not includes these substances		

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	明中给出。				
10.5	Devices shall be designed and manufactured in such a way as to reduce as far as possible the 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. 必须合理设计及生产器械，以尽量降低因物质意外进入器械而造成的风险，并且应考虑到器械及其预期使用环境的性质。	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.
10.6	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials. 器械的设计和制造应尽可能减少与颗粒尺寸和性能相关的风险，除非这些颗粒接触到的是完好的皮肤，否则这些颗粒会位于或可释放到患者或使用者体内。应特别注意纳米材料。	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.
11.	**Infection and microbial contamination 感染及微生物污染**				
11.1	Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:	A	EN 13795-3:2006, EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.

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	(a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries, (b) allow easy and safe handling, (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and (d) prevent microbial contamination of the device or its content such as specimens or fluids. 器械和制造过程的设计应尽可能消除或减少感染患者、使用者和（适用时）其他人的风险。设计应： (a) 尽可能减少并消除意外由于切割和刺破造成的风险，例如针刺损伤， (b) 使用便捷安全， (c) 尽可能降低器械的微生物泄漏和/或使用过程中的微生物暴露， (d) 防止器械或其所包含之物（例如样本或液体）受到微生物的污染。			Product test reports (Appendix 6)	
11.2	Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation. 必要时，应将器械设计成便于进行安全清洁、消毒和/或再灭菌。	N.A	The device is non sterile device for single use, no disinfection or sterilization for use.		
11.3	Devices labelled as having a specific microbial state shall	N.A	The device does not have specific microbial.		

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	be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer. 应对标记为具有特殊微生物种群的器械进行设计、制造和包装，以确保在投放到市场时，及在制造商规定的运输和储存条件下，器械依旧保持原样。				
11.4	Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user. 应根据适当流程，对在无菌状态下运输的器械进行设计、制造和包装，以确保在投放到市场时，及在制造商指定的运输和储存条件下，器械能保持无菌状态，除非旨在保持其无菌状态的包装遭到损坏，仍保持无菌，直至保护包装破损或出于使用目的而打开时。这些措施应确保最终使用者可清晰可见无菌包装的完整性。	N.A	The device is non sterile device for single use, no disinfection or sterilization for use.		
11.5	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	N.A	The device is non sterile device for single use, no disinfection or sterilization for use.		

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	应通过适当的经过验证的方法处理、制造、包装和灭菌标记为无菌器械。				
11.6	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities. 用于灭菌的器械应采用适当且可控条件和设备进行制造和包装。	N.A	The device is non sterile device for single use, no disinfection or sterilization for use.		
11.7	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer. 若器械在使用前灭菌，则非无菌器械的包装系统应保持产品的完整性和清洁度，以尽量减少微生物污染风险；此外，包装系统应适当考虑制造商指定的灭菌方法。	N.A	The device is non sterile device for single use, no disinfection or sterilization for use.		
11.8	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile. 器械标识除带有灭菌产品的指示符号外，还应可区别市场上相同或相似器械的灭菌和非灭菌状态。	N.A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.
12	**Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.**				

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	包含被认为是医药产品物质的器械，及由人体吸收或局部喷洒在人体上的物质或物质组合构成的器械				
12.1	In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation. 对于第 1(8)条第一子段所指的器械，若单独使用，则该物质的质量、安全性和可用性将被视为是符合第 2001/83/EC 号指令第 1 条(2)点的医药产品，则应按照本法规中适用的符合性评估流程的规定，使用与第 2001/83/EC 号指令附录 I 所规定方法相似的方法进行验证。	N.A	The device does not include these materials.		
12.2	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation. 预期植入到人体，以及由人体吸收或局部喷洒在人体上的物质或物质组合构成的器械，应遵从，（适用时）并受限于本	N.A	The device does not include these materials.		

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	法规与第 2001/83/EC 号指令附录 I 中规定的相关要求未涵盖方面，而这些相关要求用于按照本法规适用的符合性评估流程，对吸收、分配、新陈代谢、排泄、局部耐受性、毒性，与其他器械、医药产品呼呼其他物质和相互影响，及副作用的潜在影响进行评估。				
13.	**Devices incorporating materials of biological origin 包含生物来源材料的器械**				
13.1	For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; (b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; (c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC. 对于使用由本法规涵盖的非活性或处理为非活性人源生物组织或细胞制造成的器械，根据第 1(6)条(g)点，适用以下	N.A	The device does not include these materials.		

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	规定： (a) 对用于器械生产的人源组织和细胞的捐赠、购买和测试应根据第 2004/23/EC 号指令完成。 (b) 应对那些组织和细胞或其衍生物进行处理、保存和任何其他操作，从而为患者、使用者、（适用时）其他人员提供安全保障。特别是，应通过适当的来源方法，以及通过在制造过程中实施经验证的消除或失活方法处理与病毒和传染因子安全性相关的问题。 (c) 这些器械的可追溯体系应与第 2004/23/EC 号指令和第 2002/98/EC 号指令所规定可溯源性和数据保护要求是互补和相兼容。				
13.2	For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers; (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process,	N.A	The device does not include these materials.		

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	except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; (c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply. 对于使用非活性或处理非活性动物源组织或细胞，或其衍生物制造的器械，应适用以下规定： (a) 在可行的情况下，考虑到动物物种，动物源组织和细胞或其衍生物应来自已经受兽医控制，即适合于组织预期使用的动物。由制造商保留动物地理来源信息。 (b) 应获取动物源组织、细胞和物质或其衍生物，并对其进行处理、保存、测试和操作，从而为患者、使用者和其他人员（如适用）提供安全保障。特别是关于病毒和其他传播因子的安全性，应通过在制造过程中，实施经验证的消除或病毒灭活方法来解决，除非此类方法的使用会导致不可接受的降解，损害器械的临床益处。 (c) 在使用动物来源的组织或细胞或其衍生物制造的器械，如第 722/2012 号法规所述，应适用该法规规定的特别要求。				
13.3	For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In	N.A	The device does not include these materials.		

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	particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. 对于使用其他非活性生物物质制造的器械，在第 13.1 和 13.2 节所述的情况下，应对这些物质的进行加工、保存、测定和处理，以便为患者、使用者和其他人（如适用）提供安全性，包括整条废物处理链。特别是，应通过适当的来源方法，及通过在生产过程中实施经验证的消除或失活方法处理与病毒和传染因子安全性相关的问题。				
14.	**Construction of devices and interaction with their environment 器械构造及其与环境之间的相互作用**				
14.1	If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection. 若器械预定与其他器械或设备一起配合使用，必须保证整个系统（包括连接系统）具有安全性，同时不得改变本器械的指定性能。此类组合结构的任何使用限制应在标签和/或使用说明书上标明。应以尽量减少所有可能的风险（如误连接）的方式设计和构造使用者必须处理的连接件，例如流体、气体输送、电气或机械联轴节。	N.A	The device is used independently and no connected parts		

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14.2	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; 应采用适当方式设计和制造器械，确保尽可能地避免或减少以下内容： （a）与器械物理特征有关的伤害风险，包含体积/压力比、尺寸、和人体工程学特征（如适用）；	N.A	The device is SMS materials device		
	(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; 与可合理预见的外部影响或环境条件相关的风险，例如磁场、外部电场和电磁效应、静电放电、诊断或治疗过程的辐射、压力、湿度、温度、压力变化和压力加速或者无线电信号干扰；	N.A	The device is SMS materials device		
	(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use; 与该器械使用相关的风险，当其接触材料、液体和物质时，包括其在正常使用条件下暴露接触的气体；	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.
	(d) the risks associated with the possible negative	N.A	The device is SMS materials device		

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	interaction between software and the IT environment within which it operates and interacts; 与软件和 IT 环境间的可能负相互作用相关的风险，器械在该 IT 环境内操作和相互作用；				
	(e) the risks of accidental ingress of substances into the device; 物质意外进入器械的风险；	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.
	(f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and 在研究中正常使用或给予治疗期间，与其他器械相互干扰造成的风险；	N.A	The device is used independently		
	(g) 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. 由于下面原因导致的风险：材料老化、测试或控制机能精准度下降而无法维修或校正（如植入人体后）器械。	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02) Product test reports (Appendix 6)	Quality Dept.
14.3	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion. 必须适当地设计和制造器械，确保在正常使用期间和单一故	N.A	The device is not active device		

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	障情形下尽量减少火灾或爆炸风险。应特别留意此类器械：其预期用途包括暴露于或与易燃易爆物质或可引燃物质结合使用的器械。				
14.4	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. 器械的设计和制造应确保可安全且有效地进行调整、校准和维护。	N.A	The device does not need adjustment, calibration, and maintenance		
14.5	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe. 用于与其他器械或产品协同操作的器械设计和制造应确保其互通性和兼容性可靠且安全。	N.A	The device is used independently		
14.6	Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used. 应根据人体工程学原理设计和制造任何测量、监测或显示器标度的器械，且考虑到器械的预期用途、使用者以及器械预期使用所在的环境条件。	N.A	The device does not have measuring, monitoring function		
14.7	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which	A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.

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	their devices can be safely disposed after use. Such procedures shall be described in the instructions for use. 应以此类方式设计和制造器械，以便于使用者、患者或其他人安全处置器械和/或相关废物。为此，制造商应研究并测试程序和措施，以便器械使用后可安全处置。这些程序应在使用说明中给出。				
15.	**Devices with a diagnostic or measuring function 具有诊断或测定功能的器械**				
15.1	Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer. 应以此类方式设计和制造具有测定功能的诊断器械和器械，应根据适当的科学和技术方法为其预期用途提供足够的准确度、精度和稳定性。准确度范围应由制造商指定。	N.A	The device does not have measuring, diagnosing function		
15.2	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC. 具有监测功能的器械进行并且以合法单位表示的测量应符合理事会第80/181/EEC号指令关于成员国对于测量单位的相似法律以及废除第71/354/EEC号指令的规定。	N.A	The device does not have measuring, diagnosing function		
16.	**Protection against radiation 辐射防护**				

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16.1	General (a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. 必须适当地设计、制造和包装器械，确保在预定用途下尽量减少对患者、使用者和其他人员造成辐射，但在治疗和诊断目的使用下不对规定合理的剂量进行限制。	N.A	The device does not create radiation		
	(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified. 发出有害或潜在危险辐射的器械的操作说明应包含关于发射辐射性质、保护患者和使用者的方法，以及避免误用和尽可能和适当减少安装固有风险的详细信息。此外，还应指定有关验收试验、性能试验、验收标准以及维修保养程序的信息。	N.A	The device does not create radiation		

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16.2	Intended radiation 预期辐射 (a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. 若器械因实现特定医疗目的而不可避免地辐射危害或潜在危害水平的电离和/或非电离辐射，并且其收益一般视为超过该辐射内固有的风险，则使用者必须可控制辐射。此类器械的设计和制造应确保相关可变参数在可接受公差范围内的再现性。	N.A	The device does not create radiation		
	(b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions. 当器械用于发射有害或潜在危险的电离和/或非电离辐射时，应尽可能安装此类发射的可视显示器和/或声响报警信号。	N.A	The device does not create radiation		
16.3	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. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.	N.A	The device does not create radiation		

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	应采用适当方式设计和制造器械，确保尽可能降低患者、使用者和其他人员遭受非预期、漫辐射或散射辐射暴露。在可能和适当的情况下，应选择减少患者、使用者和可能受影响的其他人的辐射暴露方法。				
16.4	Ionising radiation 电离辐射 (a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. (b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. (a) 旨在发射电离辐射的器械的设计和制造应考虑到第 2013/59/Euratom 号指令的要求，其中规定了防止由于暴露于电离辐射而产生危险的基本安全标准。 (b) 旨在发射电离辐射的器械的设计和制造应确保（如可能）考虑到可在治疗期间改变和控制和（如可能）监测所发射辐射的预期用途、数量、几何形状和质量。	N.A	The device does not create radiation		
	(c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.	N.A	The device does not create radiation		

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	(d) Devices that emit ionising radiation and are 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, energy and, where appropriate, the quality of radiation. (c) 若会发射离子辐射的器械预定用于放射医学诊断，则应采用适当方式设计和制造器械，确保获得符合预期医疗用途的合适图像和/或输出质量，同时尽量减少对患者和使用者的辐射。 (d) 若会发射离子并预定用于放射医治的器械，则应采用适当方式设计和制造器械，确保可监控和控制器械辐射剂量、光束类型和能量以及辐射质量（如适用）。				
17.	**Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves** **可编程电子系统——包含可编程电子系统的器械与本身就是器械的软件**				
17.1	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance. 包含可编程电子系统（包括软件）的器械或者自身为器械的软件，其设计应根据其预期用途确保相应可重复性、可靠性和性能。在单一故障条件下，应采取适当手段以尽可能消除或降低由此造成的风险或性能损害。	N.A	The device is not active device without software		

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17.2	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation. 针对包含软件的器械或自身为器械的软件，应根据现有技术开发和制造软件，同时考虑开发生命周期原则、风险管理，包括信息安全、验证和确认。	N.A	The device is not active device without software		
17.3	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise). 本节所指软件用于与移动计算平台结合使用，其设计和制作应考虑移动平台的具体特征（如，屏幕的大小和对比度）以及与其用途相关的外部因素（环境变化，如光照或噪声水平）。	N.A	The device is not active device without software		
17.4	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. 制造商应规定有关硬件、IT 网络特性和 IT 安全措施的最低要求，包括防止非授权访问、按预期运行软件的必要条件。	N.A	The device is not active device without software		
18.	**Active devices and devices connected to them 有源器械和与其连接的器械**				

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18.1	For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks. 对于非植入式有源器械，在出现单一故障情况时，应采取适当的措施尽可能消除或减少由此产生的风险。	N.A	The device is not active device without software		Quality Dept.
18.2	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical. 当患者的安全性取决于内部电源时，此类器械应配备可确定电源状态的手段，并且当电源容量处于临界值时。必要时应在电源容量变为临界值之前，提供适当警告或指示。	N.A	The device is not active device without software		Quality Dept.
18.3	Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure. 若患者安全取决于外部供电，器械必须包含一个报警系统，用于指示任何电力故障。	N.A	The device is not active device without software		Quality Dept.
18.4	Devices intended to monitor one or more clinical parameters of a patient shall 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. 若器械预定用于监测患者内一个或多个临床参数，器械必须配备适当报警系统，用于提供有关可导致患者死亡或健康状态严重恶化的警戒信息给使用者。	N.A	The device is not active device without software		Quality Dept.
18.5	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating	N.A	The device is not active		Quality Dept.

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	electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment. 器械的设计和制造应尽可能降低产生电磁干扰的风险，以免影响相关器械或该使用环境下其他器械或设备的操作。		device without software		
18.6	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended. 器械的设计和制造应提供充足的抗电磁干扰天然免疫水平，使其足以使器械按预期操作。	N.A	The device is not active device without software		Quality Dept.
18.7	Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer. 器械的设计和制造应尽可能避免在正常使用器械期间和在单一故障情况下对患者、使用者或任何其他人造成意外电击危险，但前提是器械须按照制造商的指示安装和维护保养。	N.A	The device is not active device without software		Quality Dept.
18.8	Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended. 器械的设计和制造应尽可能保护对器械的未经授权访问，以免器械无法正常运行。	N.A	The device is not active device without software		Quality Dept.
19.	**Particular requirements for active implantable devices 有源可植入器械的特殊要求**				
19.1	Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as	N.A	The device is not active device without software		

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	far as possible: (a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, (b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and (c) risks which may arise where maintenance and calibration are impossible, including: — excessive increase of leakage currents, — ageing of the materials used, — excess heat generated by the device, — decreased accuracy of any measuring or control mechanism. 应采用适当方式设计和制造有源可植入器械，确保尽可能地避免或减少： (a) 根据特定参考文献，与使用能源相关的风险，如使用电力，器械的绝缘、漏泄电流和过热风险， (b) 与医疗有关的风险，特别是使用除颤器或高频外科手术器械产生的风险， (c) 在不可能进行维护和校准时可能出现的风险，包括： - 漏泄电流过度增大， - 所使用材料的老化， - 器械产生的过热， - 测量或控制机制准确性降低。				
19.2	Active implantable devices shall be designed and manufactured in such a way as to ensure — if applicable, the compatibility of the devices with the	N.A	The device is not active device without software		

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	substances they are intended to administer, and — the reliability of the source of energy. 有源可植入器械的设计和制造应确保 - 如适当，器械与其预期施用物质的兼容性， - 能源的可靠性。				
19.3	Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts. 有源可植入器械（如适当）及其组成部分应可识别，以便允许在发现与器械或其组成部分相关的潜在风险之后采取任何必要的措施。	N.A	The device is not active device without software		
19.4	Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation. 有源可植入器械应附带可明确识别自身及其制造商的代码（特别是关于器械的类型和制造年份）；若必要，应可读取该代码，而不需要进行外科手术。	N.A	The device is not active device without software		
20.	**Protection against mechanical and thermal risks 机械和热风险防护**				
20.1	Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts. 应采用适当方式设计和制造器械，确保防止患者和使用者遭	N.A	The device is non-woven materials device		

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	受与机械特征有关的机械风险，例如：运动阻力、稳定性或运动部件等。				
20.2	Devices shall 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. 应采用适当方式设计和制造器械，确保尽量降低因器械振动引起的风险水平，并考虑利用先进技术和手段限制振动（尤其振动源处），除非振动是规定性能中一部分。	N.A	The device is non-woven materials device		
20.3	Devices shall 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. 应采用适当方式设计和制造器械，确保尽量降低因噪音释放而产生的风险水平，并考虑利用先进技术和手段减少噪音（尤其噪音源处），除非这种噪音是规定性能中组成部分。	N.A	The device is non-woven materials device		
20.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks. 若使用者或他人必须操作连接到电力、气体、液压或气动能量供给源的端子和连接器，应采用适当方式设计和构造此类端子和连接器，确保尽量降低任何潜在风险。	N.A	The device is non-woven materials device		

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20.5	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk. 当安装或重装某些部件时可能出现的失误将有可能成为风险的源头，此类部件的设计和构造应完全避免该风险，若无法实现，则应通过在部件和/或其外壳的信息说明。 当需要知道移动方向以避免风险，相同信息应在活动部件和/或其外壳说明。	N.A	The device is non-woven materials device		
20.6	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use. 在正常使用条件下，器械内可接触部件（不包括拟供热或达到给定温度的部件或区域）及其周围可触及部件不会达到造成危险的温度。	N.A	The device is non-woven materials device		
21.	**Protection against the risks posed to the patient or user by devices supplying energy or substances** **通过器械供应能量或物质防止对患者或使用者造成危险**				
21.1	Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.	A	EN ISO 14971:2012, ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	若器械预定用于为患者供给能量或物质，应采用适当方式设计和制造器械，确保能够准确地设置和维持输送量，从而足以保证患者和使用者的安全。				
21.2	Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source. 器械应配备防止和/或指示输送可能产生危险的能量或物质数量方面的任何不足。器械必须集成适当手段，确保尽可能地防止危险等级的能源或物质从能源及/或物质来源中泄漏。	N.A	The device does not output danger substance		
21.3	The function of the controls and indicators shall 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 shall be understandable to the user and, as appropriate, the patient. 控制器和指示器功能必须明确地注明在器械上。若器械提供使用说明或者通过一个可视系统指示操作或调整参数，必须保证使用者和患者（如适用）易于理解这些信息。	N.A	The device is not active device		
22.	**Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons** **防止制造商预期用于非专业人员使用的医疗器械所造成的危险**				
22.1	Devices for use by lay persons shall be designed and manufactured in such a way that they perform	A	EN ISO 14971:2012, EN 62366-1:2015+AC:2015	Risk analysis report XTDC/CE03-01-07	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply. 由非专业人员使用的器械的设计和制造应使其适用于预期用途，其中考虑到可用于专业人员的技能和方法以及在非专业人员的技术和环境中合理预期差异导致的影响。制造商提供的信息和说明应易于非专业人员理解和应用。			Usability Evaluation (XTDC/CE03-01-04)	
22.2	Devices for use by lay persons shall be designed and manufactured in such a way as to: — ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information, — reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and — reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results. 由非专业人员使用的器械的设计和制造应： - 确保目标使用者在适当训练和/或信息获得后的所有必要治疗阶段均可安全且准确使用器械；和 - 尽可能减少并消除意外由于切割和刺破造成的风险，例如针刺损伤；和 - 尽可能减少预期使用者在处理器械以及（如适当）在结	A	EN ISO 14971:2012, EN 62366-1:2015+AC:2015 ISO 13485:2016	Risk analysis report XTDC/CE03-01-07 Usability Evaluation (XTDC/CE03-01-04) Design and Manufacturing Control (XTDC/CE03-01-02)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	果解读中的错误风险。				
22.3	Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: — can verify that, at the time of use, the device will perform as intended by the manufacturer, and — if applicable, is warned if the device has failed to provide a valid result. 由非专业人员使用的器械（如适当）应包括非专业人员使用的规程 - 在使用时，可验证器械将按照制造商的意图工作，并且 - 如适当，若器械未能提供有效的结果，则发出警告。	A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.
III.	**CHAPER III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE 有关器械随附信息的要求**				
23.	**Label and instructions for use 标签和使用说明书**				
23.1	General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following: 制造商需提供的信息的一般要求 各器械应附有识别器械及其制造商所需的信息，	A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	并酌情将安全与性能信息传达给使用者或其他人。此类信息可能出现在器械本身、包装上或使用说明书中，若制造商有网站，则应在网站上提供并保持更新最新信息，同时考虑到以下因素：				
	(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. 标签和使用说明的介质、格式、内容、易读性和位置应适合于特定器械、其预期目的和对预期使用者的技术知识、经验、教育或培训。尤其是，使用说明书应以预期使用者容易理解的语言撰写，并且在适当时，补充图纸和图表。	A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.
	(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. 标签上所需的信息应在器械本身上提供。若不可行或不适当，则某些或所有信息可显示在各单元的包装上和/或多个器械的包装上。	A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按 医 疗 器 械 法 规 （MDR） 附 录 一 的 基 本 要 求 检 查 表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes. 标签应以人类可读的格式提供，并可通过机器可读信息，例如射频识别（"RFID"）或条形码来补充。	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section. 使用说明应与器械一起提供。例外情形：对于 I 类和 IIa 类器械，若在无使用说明书的情形下同样可安全地使用器械，则无需此类使用说明书。除非本节其他地方另有规定。	A	EN 1041:2008,	Instruction for use (IFU-XTDC03)	Quality Dept.
	(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge. 当向单个使用者和/或位置提供多个器械时，若购买者同意，则可提供使用说明的单个副本，但购买者在任何情况下可请求免费提供其他副本。	A	EN 1041:2008,	Instruction for use (IFU-XTDC03)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation. 若根据第207/2012号法规或根据本法规通过的任何后续实施规则中规定的条件，可向使用者提供非纸质格式（例如，电子格式）使用说明。	A	EN 1041:2008,	Instruction for use (IFU-XTDC03)	Quality Dept.
	(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer. 需要传达给使用者和/或其他人的剩余风险应包括作为制造商所提供信息中的限制、禁忌症、预防措施或警戒。	A	EN 1041:2008,	Instruction for use (IFU-XTDC03)	Quality Dept.
	(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device. 如适当，制造商提供的信息应采用国际公认的符号形式。使用的任何符号或识别颜色应符合协调标准或 CS。若未协调标准或 CS，符号和颜色应说明在随同器械提供的文	A	EN ISO 15223-1:2016, EN 1041:2008,	Label (Label-XTDC03) Instruction for use (IFU-XTDC03)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	件中。				
23.2	Information on the label 标签上的信息 The label shall bear all of the following particulars: 标签必须注明下面全部事项：	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(a) the name or trade name of the device; 器械的名称或商品名称；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device; 使用者识别器械所必需的详细信息、包装内容以及对于使用者不明显的器械预期用途；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; 制造商的名称、注册商号或注册商标及其注册营业地点的地址；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative; 授权代表的姓名和授权代表的注册营业地点地址（若制造商在欧盟以外有其注册营业地点）；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	(e) where applicable, an indication that the device contains or incorporates: — a medicinal substance, including a human blood or plasma derivative, or — tissues or cells, or their derivatives, of human origin, or — tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012; 如适当，器械包含或采用的指示信息， — 药物，包括人血或血浆衍生物或 — 人源的组织或细胞或其衍生物或 — 动物源的组织或细胞或其衍生物，如第 722/2012 号法规所述。	N.A	The device does not contain these substance or materials		
	(f) where applicable, information labelled in accordance with Section 10.4.5.; 如适当，标签信息应符合第10.4.5节规定；	N.A	The device does not includes these substances		
	(g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; 批号或前面带有词语 LOT NUMBER 或 SERIAL NUMBER 的器械的序列号或等效符号（如适用）；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII; 根据第 27(4)条和附录 VII 第 C 部分的 UDI；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	(i) an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant; 明确指示可安全使用或植入器械的时间限制，至少表示为与之相关的年份和月份；	N.A	The device does not need these indication		
	(j) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable; 若没有指明可安全使用的日期，则指明制造日期。若日期清晰可辨，制造日期可作为批号或序列号的一部分；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(k) an indication of any special storage and/or handling condition that applies; 指明适用的任何特殊储存和/或处理条件；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method; 若以无菌方式提供器械，还应指示其无菌状态和灭菌方法；	N.a	The device is non-sterile device		
	(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.

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	use, taking into account the intended users; 需要立即引起器械使用者和任何其他人的注意、需要采取的警戒或预防措施。该信息可保持最小量，在这种情况下，更详细的信息将出现在使用说明中，同时考虑到预期使用者；				
	(n) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union; 若器械用于一次性使用，则相应指明。制造商的一次性使用指示应在整个欧盟内保持一致；	A	EN ISO 15223-1:2016	Label (Label-XTDC03)	Quality Dept.
	(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles; 若器械是已进行再处理的一次性使用器械，提供该事实的指示信息、已执行的再处理循环次数以及关于再处理循环次数的任何限制；	N.A	The device is only for single use, no reprocessed allowed		
	(p) if the device is custom-made, the words 'custom-made device'; 若器械是定制的，则提供词语"定制器械"；	N.A	The device is not customized device		
	(q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation'; 指示信息，用于指示器械为医疗器械。若本器械	N.A	The device is not for clinical investigation use.		

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	仅预定用于临床研究，应标明“临床研究专用”；				
	(r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action; 若器械包含预计经由身体孔口引入人体或施加在皮肤上，并被人体吸收或局部喷洒在人体上的物质或物质组合，则提供器械的整体定量成分和负责实现主要预期作用的主要成分的定量信息；	N.A	The device is non-invasive device, and no substances introduced into human body		
	(s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number. 对于有源可植入器械，提供序列号，对于其他可植入器械，提供序列号或批号。	N.A	The device is not active device.		
23.3	Information on the packaging which maintains the sterile condition of a device (‘sterile packaging’) The following particulars shall appear on the sterile packaging: 关于保持器械无菌条件的包装信息（“无菌包装”）： 无菌包装上应出现以下细节：	N.A	The device is non-sterile device.		
	(a) an indication permitting the sterile packaging to be recognised as such, 指明无菌包装标识，	N.A	The device is non-sterile device.		

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	(b) a declaration that the device is in a sterile condition, 声明该器械处于无菌状态，	N.A	The device is non-sterile device.		
	(c) the method of sterilisation, 灭菌方法，	N.A	The device is non-sterile device.		
	(d) the name and address of the manufacturer, 制造商名称和地址，	N.A	The device is non-sterile device.		
	(e) a description of the device, 器械说明，	N.A	The device is non-sterile device.		
	(f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations', 若本器械仅预定用于临床研究，应标明"临床研究专用"，	N.A	The device is non-sterile device and not for clinical investigation use		
	(g) if the device is custom-made, the words 'custom-made device', 若属于定制器械，应标明"定制器械"，	N.A	The device is non-sterile device and not customized device.		
	(h) the month and year of manufacture, 制造月份和年份，	N.A	The device is non-sterile device.		
	(i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and 安全使用或植入器械的时间限制的明确指示信息，并表示为与之相关的年份和月份；	N.A	The device is non-sterile device.		
	(j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. 检查使用说明的说明，即若无菌包装损坏或在使用前不小心打开，该如何处理。	N.A	The device is non-sterile device.		
23.4	Information in the instructions for use The instructions for use shall contain all of the following particulars:	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.

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	1.1.1 使用说明书中的信息 使用说明应包含以下全部详细规定：				
	(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2; 第 23.2 节第（a）、（c）、（e）、（f）、（k）、（l）、（n）和（r）点所述的详细规定；	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate; 器械的预期用途具有适应症、禁忌症、患者目标群体和预期使用者（如适用）的明确规范；	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(c) where applicable, a specification of the clinical benefits to be expected. 如适用，提供预期的临床收益规范；	N.A	No need for the device		
	(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32; 如适用，提供按照第 32 条的安全和临床性能总结链接；	N.A	No need for the device		
	(e) the performance characteristics of the device; 器械的性能特征；	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(f) where applicable, information allowing the health care professional to verify if the device is suitable and select the corresponding software and accessories; 如适用，提供信息用于医疗保健专业人员验证器械是否合适，并选择相应的软件和附录；	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.

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	任何剩余风险、禁忌症和任何不良副作用，包括传达给患者的关于这方面的信息；				
	(h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it; 使用者适当地使用器械的要求规范，例如，若器械具有测定功能，提供其所要求的准确度；	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection; 在准备使用之前或在其使用（例如，灭菌、最终组装、校准等）期间器械的任何预处理或处理的细节，包括确保患者安全所需的消毒水平和实现那些消毒水平所需的所有可用方法；	N.A	Not pre-use treatment needed		
	(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; 所有特殊设施的任何要求或特殊培训或器械使用者和/或其他人的特定资格；	N.A	No special requirements		
	(k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection, — identification of any consumable components and how to replace them,	N.A	The device does not need install		

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	— information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and — methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices; 验证器械是否正确安装并是否准备好安全以及按制造商意图执行的信息（若相关）： -预防和定期维护以及任何预备清洁或消毒的性质和频率的详细信息； -任何消耗部件的标识和更换方法； -任何必要的校准信息，其用以确保器械在其预期寿命期间正常和安全地工作； -消除参与安装、校准或维修器械的人所遇到风险的方法。				
	(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; 若提供的器械是无菌的，则无菌包装在使用前被损坏或无意打开的情况下，应提供说明；	N.A	The device is non-sterile device		
	(m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; 若提供的器械是非无菌的，并且需要在使用前进行灭菌，应提供适当的灭菌说明；	N.A	The device does not need sterilization before use		
	(n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused,	N.A	The device is for single use		

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	e.g. signs of material degradation or the maximum number of allowable reuses; 若器械可重复使用，提供重复必需的适当处理过程的相关信息，包括清洁、消毒、包装以及（如适当）经过验证的适用于器械投放市场所在成员国的重新灭菌方法。应提供信息以识别该器械何时不得再使用，例如，材料劣化迹象或允许重复使用的最大数量。				
	(o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements; 必要的指示信息，指示只有在制造商负责进行重新调整后符合通用安全与性能要求，方可重复使用该器械。	N.A	The device is for single use		
	(p) if the device bears an indication that it 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. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request; 若器械带有一次性使用指示，在重复使用器械的情形下，制造商已知的特性和技术因素相关信息可能会构成风险。此信息应基于制造商风险管理文档的特定部分，应详细说明这些特征和技术因素。若按照第 23.1 节(d)点无需任何使用说明，该信息必须按要求提供给使用者。	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(q) for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in	N.A	The device is for independent use		

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	order to obtain a safe combination, and/or — information on any known restrictions to combinations of devices and equipment; 对于旨在与其他器械和/或通用设备一起使用的器械： -信息用于识别这些器械或设备，以便获得安全组合，和/或 -有关器械和设备组合的任何已知限制的信息。				
	(r) if the device emits radiation for medical purposes: — detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, — the means of protecting the patient, user, or other person from unintended radiation during use of the device; 若器械发出辐射用于医疗用途： -关于发出辐射的性质、类型和（如适当）强度和分布的详细信息； -防止患者、使用者或其他人在使用器械期间受到意外辐射的方法。	N.A	The device does not emit radiation		
	(s) information that allows the user and/or patient to be informed of any warnings, precautions, contra- indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate: — warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety, — warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.

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	magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, 有关允许向使用者和/或患者通知任何警戒、预防措施、禁忌症、待采取措施以及与器械有关的使用限制信息。在相关情况下，此信息应允许使用者向患者简述所有警戒、预防措施、禁忌症、待采取措施以及与器械有关的使用限制。该信息应酌情包括： —器械发生故障或可能会影响安全的性能变化时的警戒、预防措施和/或待采取措施； —警戒、预防措施和/或就暴露于合理可预见的外部影响或环境条件采取的措施（例如磁场、外部电和电磁效应、静电放电、与诊断或治疗过程相关的辐射、压力、湿度、或温度；				
	— warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, —在特定诊断研究、评估或治疗处理或其他程序（例如，由影响其他设备的器械所发出的电磁干扰）期间，器械的合理可预见存在所造成的干扰风险的警戒、预防措施和/或待采取措施；	N.A	The device does not have these function		
	— if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,	N.A	The device doesn’t contain these substance or materials		

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	—若器械用于管理人或动物来源的生物物质药品、组织或细胞或其衍生物，则在选择交付物质时需考虑任何可能的限制或不相容性；				
	— warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and —结合到器械中作为器械组成部分的药物或生物材料相关的警戒、预防措施和/或限制；	N.A	The device doesn't contain these substance or materials		
	— precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user; —与纳入器械的 CMR 或具有内分泌干扰性质或可能导致患者或使用者的致敏或过敏反应的材料相关的预防措施；	N.A	The device doesn't contain these substance or materials		
	(t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose; 若拟引入人体并由人体吸收或局部扩散在人体内的物质或物质组合构成，则该器械及其代谢产物产品与其他器械、药品和其他物质间相互作用的一般概况以及禁忌、不良副作用和过量风险的警戒和预防措施（如适用）。	N.A	The device does not introduce substance into human body		
	(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials	N.A	The device is not implantable device		

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	and substances to which patients can be exposed; 对于可植入器械，有关患者可暴露材料和物质的总体定性和定量信息；				
	(v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and — physical hazards such as from sharps. If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request; 为便于安全处理器械、其附录和与其一起使用的耗材（如有），应采取的警戒或预防措施。该信息应酌情包括： —感染或微生物危害（例如，被人源潜在感染性物质污染的外植体、针或手术器械）； —物理性危害（例如来自尖锐物）。 若可按照第 23.1 节（d）点要求无使用说明，则应根据要求将这些信息提供给使用者；	N.A	The device is for independent use		
	(w) for devices intended for use by lay persons, the circumstances in which the user should consult a health care professional; 对于非专业人员使用的器械，使用者应咨询医护专业人员；	N.A	The device can be used by lay person		
	(x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device; 对于根据本法规第 1(2)条涵盖的器械，关于缺乏临床收益以及与器械使用相关的风险信息；	N.A	The device is not these device		

Checklist according to annex I of the Medical Device Regulation (MDR) 按医疗器械法规（MDR）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	(y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use; 使用说明的发布日期，若已修订，最新版本使用说明的发布日期和标识符；	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established; 向使用者和/或患者发出关于与器械有关的任何严重事件的通知，应报告给使用者和/或患者所在成员国的制造商和主管当局；	A	EN 1041:2008	Instruction for use (IFU-XTDC03)	Quality Dept.
	(aa) information to be supplied to the patient with an implanted device in accordance with Article 18; 根据第 18 条向患者提供有关植入器械的信息；	N.A	The device is not implantable device		
	(ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. 对于结合可编程电子系统的器械，包括软件或器械本身是软件，有关硬件、IT 网络特性和 IT 安全措施的最低要求（包括防止未经授权的访问）对于运行软件来说所必要的；	N.A	The device does not include software		

Indications for Use

Doc number: IFU-XTDC03, Ver.1.0, effective date: 2020-05-06

Product Name: Medical isolation gown
Type: PP+PE, PP, SMS, PE
Indications For Use:
The medical device is intended to be worn by healthcare providers or visitors to isolate themselves from patients, helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Single-use, Non-sterile.
Contraindications: Users who is allergic to PP+PE, PP, SMS, PE materials.
Specifications:

Material	PP+PE, PP, SMS, PE		
Model	S	M	L
L x W（cm)	110x130	115x137	120x140
Sleeves (cm)	56	56	56
Cuff (cm)	16	16	16
Deviation (cm)	± 1.5	± 1.5	± 1.5

Method of Use:

- Please choose appropriate size for yourself on reference the specification table above mentioned;
- Check the package, do not use it if there are break, discoloration, stains;
- Wearing Medical isolation gown: Put your hands into the sleeve and pull back from the chest, and fasten the belt in the neck and the lower back.
- Taking off Medical isolation gown: disclose the placket, pull down the zipper to the bottom; take off the sleeve; roll the gown from top to bottom during taking off, the pollution side inward; finally put the Medical isolation gown into medical waste bag;
- The Medical isolation gown is not recommended to use over 8 hours, once damage happen during use, it shall immediately change a new one.

Limitation of use:
The product can not withstand a large amount of liquid spray
Precautions:

- The device shall be worn and taken off in defined area;
- Check the package before use, and also check the package label, production date, expiry data, and use the device in valid shelf life;
- Use the device shall be used immediately after opening package;
- To prevent to touch outside of the device before taking off protective gloves, once taking off, the glove shall try to contact the interior side of Medical isolation gown; the Medical isolation gown interior side shall outward once taking off so as to

wrap the exterior side and pollution substance inside to avoid pollution substance contacting human body and environment. The taken off device shall be disposed together, avoid expanding pollution during disposal process;

- The device is only for single use, repeated use is forbidden, after use, it shall dispose it according to local regulations.
- The Medical isolation gown can not be washed, washing will impact use performance; also, the device can not be dry washed or ironed;
- The Medical isolation gown does not conduct flame retardant test, Do not use in case of flammability.

Product Validity: 3 years

Production date, lot number: refer to product packaging

Storage requirements:

The device should be stored in a cool, dry environment, the relative humidity under 80%, to avoid direct sunlight. Do not mix with anything toxic, harmful, smell, volatile.

Transport requirements:

Transport process should avoid the sun, rain, handling should be lightly put, is strictly prohibited throw, impact, squeeze.

Contact info:

XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD
LIUKOU INDUSTRIAL PARK, XIANTAO CITY, HUBEI PROVINCE, CHINA

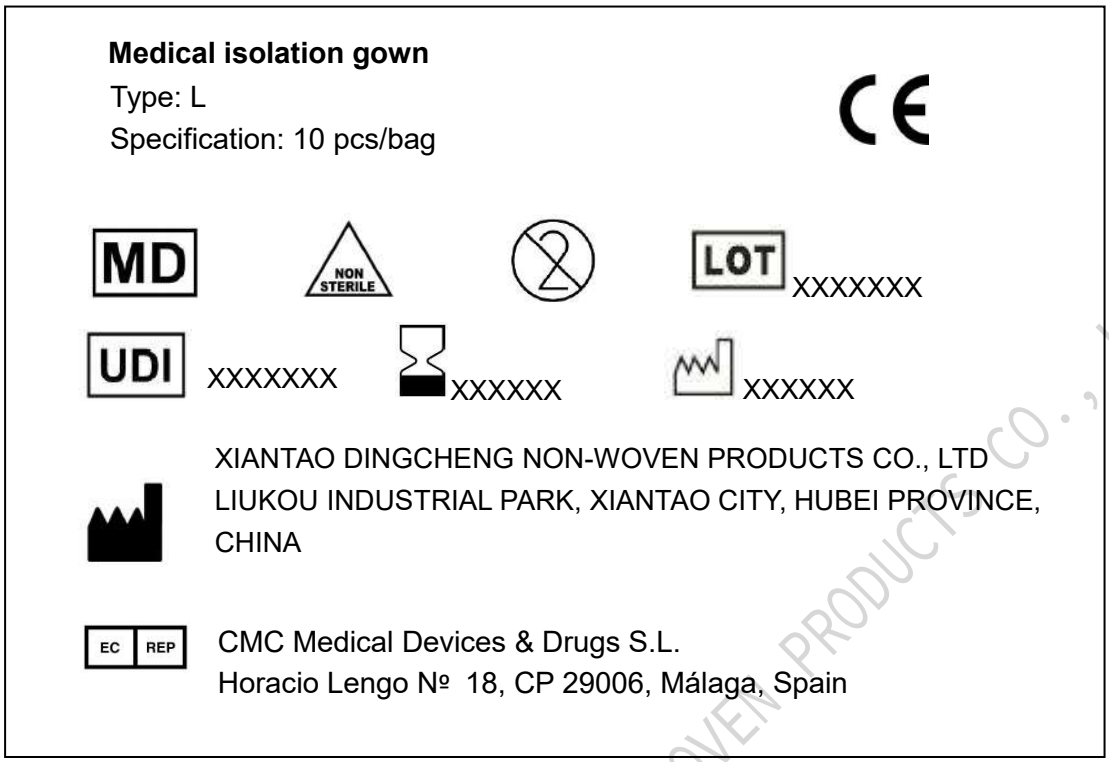
CMC Medical Devices & Drugs S.L.
Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Symbol on the

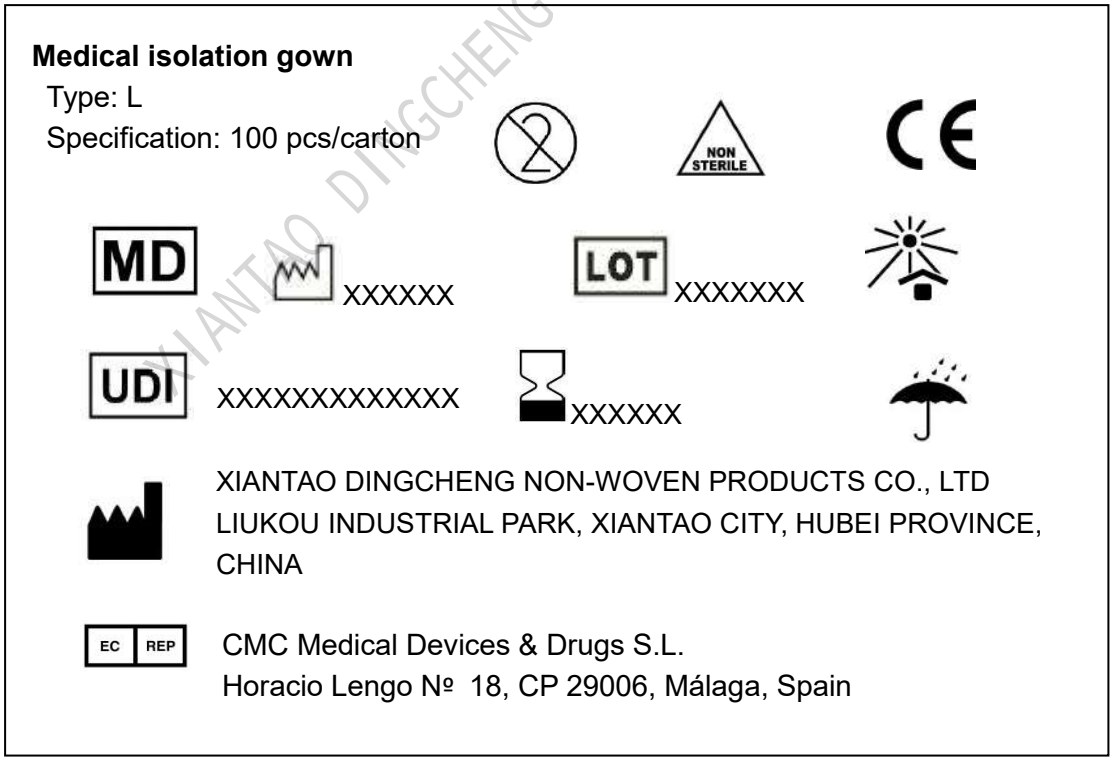
CE	CE mark		Manufacturer
EC REP	EU representative	MD	Medical device
NON STERILE	Non-sterile	UDI	UDI
	Used by		Avoid sunlight
	Keep dry		Single use
	Manufacture date	LOT	Lot number

Label-XTDC03, ver 1.0

1, The label sample for internal package



2, The label sample for external package



Risk analysis report

Compiled by:	Wang Manzhen	Date:	2020-05-06
Reviewed by:	Du Jianmin	Date:	2020-05-06
Approved by:	Cheng Qin	Date:	2020-05-06

Document History Summary

No	Summary of Changes	Effective Date	Version
1	New established	2020-05-06	A/0
2			

1. Summary

This document is a risk analysis for the Medical isolation gown. All hazards and each potential reason causing the relevant hazard have been judged in this document. This document also estimates the degree of harm caused by all kinds of hazards and the probability of occurrence of the hazards. If there are acceptable ways to reduce the risk, description have been made and the remaining risk level after making the ways has been estimated.

Result: By means of considerable ways, all risk, which may cause hazard, are reduced to an acceptable level, and the total number of all kinds of hazards is reduced to an acceptable level. Risk is proportional to usability.

2. Reference document

1. MDR (EU) 2017/745
2. EN ISO14971:2012
3. Risk Analysis Plan

3. Description of the Medical isolation gown

Product name: Medical isolation gown

Intended use:

The medical device is intended to be worn by healthcare providers or visitors to isolate themselves from patients, helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Single-use, Non-sterile.

Contraindications:

Users who is allergic to PP+PE, PP, SMS, PE materials.

Specifications: PP+PE, PP, SMS, PE

Validity of Medical isolation gown: 3 years

GMDN code: 35492

UMDN code: 15037

Applied standards:

No.	Standard	Name of document
1	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
2	EN 1041:2008	Information supplied by the manufacturer of medical devices
3	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices.
4	EN 13795-2:2019	Surgical clothing and drapes - Requirements and test methods -Part 2 Clean air suits
5	ISO 9073-10:2003	Surgical drapes, gowns and clean air suits for patients, clinical staff and equipment - Part 4: Test method for linting in the dry state
6	EN ISO 22612:2005	Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration
7	ISO 22610:2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine

		the resistance to wet bacterial penetration
8	EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
9	ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing
10	ISO 10993-5:2009	Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity
11	ISO 10993-10:2010	Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction
12	ASTM D4169-2016	Standard practice for performance Testing of Shipping Containers and Systems
13	MDCG 2019-15	Guidance notes for manufacturers of class I medical devices
14	GB 19082-2009	Technical requirements for single-use protective clothing for medical use (China)

Product performance and description:

Material	PP+PE, PP, SMS, PE		
Model	S	M	L
L x W（cm)	110x130	115x137	120x140
Sleeves (cm)	56	56	56
Cuff (cm)	16	16	16
Deviation (cm)	± 1.5	± 1.5	± 1.5

Technical performance

Item	Technical parameters
Appearance	The Medical isolation gown shall be clean, no foreign matters, no stain.
Dimensions	It shall comply the specification requirements.
Resistance to microbial penetration - Dry	≤ 2 Log_{10} (CFU)
Cleanliness - Mircrobial	≤ 2 Log_{10} (CFU/dm^2)
Cleanliness - Particulate matter	≤ 3,5 IPM
Linting	≤ 4,0 Log_{10} (lint count)
Bursting strength - Dry	≥ 40kPa
Tensile strength - Dry	≥ 20N
Moisture permeability ($g/(m^2.24h)$	≥ 2500
Impermeability (kPa)	≥1.67
Breaking force (N) Longitudinal direction	≥45

Transverse direction	≥45
Elongation at break Longitudinal direction Transverse direction	 ≥15 ≥15
Water staining (class)	≥3
Vertical combustion 4) After-flame time(s) Longitudinal direction Transverse direction 5) Continuous flame times (s) Longitudinal direction Transverse direction 6) Damaged length (mm) Longitudinal direction Transverse direction	 ≤10 ≤10 ≤15 ≤15 ≤200 ≤200

Storage conditions

The device should be stored in a cool, dry environment, the relative humidity under 80%, to avoid direct sunlight. Do not mix with anything toxic, harmful, smell, volatile.

4. Responsible group

The group of risk analysis consists of the following person:

Name	Title	Responsibility	Authority
Chen Peng	General manager	General control of Risk management	Approve the risk management plan and risk management report.
Cheng Qin	Management Representative	Risk management for product realization phase	Review and implement the risk management plan
Wang Manzhen	Tech & Quality manager	Risk management for product realization phase	Review and implement the risk management plan
Du Jianmin	Production & Purchasing manager	Risk management for product realization phase	Review and implement the risk management plan
Li Dingshan	Marketing manager	Risk management for post-marketing surveillance phase	Review and implement the risk management plan
Wang Manzhen	Tech & Quality manager	Prepare the Risk analysis report XTDC/CE03-01-07	/

5. Determination list of relative risk characteristics

Questions on determinate characteristics that will influence safety of the medical instrument.

Characteristics which may affect Product safety	If applicable, please instruct
C1. What is the intended use and how is the medical device to be used?	The medical device is intended to be worn by healthcare providers or visitors to isolate themselves from patients, helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Single-use, Non-sterile.
C2 Is the medical device intended to be implanted?	N.A, the device is not intended to be implanted.
C3 Is the medical device intended to be in contact with the patient or other persons?	Contact with patients directly in short term
C4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	PP+PE, PP, SMS, PE,
C5 Is energy delivered to or extracted from the patient?	N.A
C6 Are substances delivered to or extracted from the patient?	N.A
C7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	N.A. The device does not process biological materials.
C8 Is the medical device supplied sterile or intended to be sterilized by the user or are other microbiological controls applicable ?	No sterile product
C9 Is the medical device intended to be routinely cleaned or disinfected by the user?	N.A
C10 Is the medical device intended to modify the patient environment?	N.A.
C11 Are measurements taken?	N.A.
C12 Is the medical device interpretative?	N.A.
C13 Is the medical device intended for use in conjunction with other medical devices, machines or medical technologies?	N.A
C14 Are there unwanted output of energy or substances?	N.A
C15 Is the medical device susceptible to environmental influences?	Pay attention to the integrality of inside-packing when moving; Storage needs ventilation; avoid direct sunlight.
C16 Does the medical device influence the	Unreasonable disposal will impact the environment

environment?	
C17 Are there essential consumables or accessories associated with the medical device?	For single use
C18 Is maintenance or calibration necessary?	N.A.
C19 Does the medical device contain software?	N.A.
C20 Does the medical device have a restricted shelf-life?	1year
C21 Are there any delayed or long term use effects?	Long-term use cause loss of performance
C22 To what mechanical forces will the medical device be subjected?	N.A
C23 What determine the lifetime of the medical device?	Aging of Medical isolation gown materials
C24 Is the medical device intended for single use?	Single-use
C25 Is safe decommissioning or disposal of the medical device necessary?	N.A
C26 Does installation or use of the medical device require special training or special skills?	N.A.
C27 How will information for safe use be provided?	Label
C28 Will new manufacturing processes need to be established or introduced?	N.A
C29 Is successful application of the medical device critically dependent on human factors such as the user interface?	N.A.
C29.1 Can the user interface design features contribute to use error?	N.A
C29.2 Is the medical device used in an environment where distractions can cause use error?	N.A.
C29.3 Does the medical device have connecting parts or accessories?	N.A.
C29.4 Does the medical device have a control interface?	N.A.
C29.5 Does the medical device display information?	N.A.
C29.6 Is the medical device controlled by a menu?	N.A.
C29.7 Will the medical device be used by	N.A.

persons with special needs?	
C29.8 Can the user interface be used to initiate user actions?	N.A
C30 Does the medical device use an alarm system?	N.A.
C31 In what way(s) might the medical device be deliberately misused?	N.A
C32 Does the medical device hold data critical to patient care?	N.A.
C33 Is the medical device intended to be mobile or portable?	N.A
C34 Does the use of the medical device depend on essential performance?	The Medical isolation gown performance based on materials performance

6. Hazards determination

6.1 Judgment of possible hazard

There following list in annex D of EN ISO14971:2012 to be used as auxiliary tool for determination of potential hazards. According to definitions of this risk control, some of the contents in following form are of hazards, while some are only causes of the risks, therefore haven't been analyzed as hazard or causes of the hazards.

Please pay attention to the relation between each item and the device, as well as in which hypothetic hazard or hazard cause the factor should be taken into account.

Energy hazards and contributory factors	Reasons
electricity	**----**
heat	**----**
mechanical force	**----**
ionizing radiation	**----**
non-ionizing radiation	**----**
electromagnetic fields	**----**
moving parts	**----**
suspended masses	**----**
failure of patient-support device	**----**
pressure(e.g. vessel rupture)	**----**
acoustic pressure	**----**
vibration	**----**
magnetic fields(e.g. MRI)	**----**

biological hazards and contributory factors	**Reasons**
bio-contamination	1. The bio-burden on the product exceeds the limit 2. Imperfect sterilization cause the product

	micro-polluted 3. Pollution in packing, storage and transport
bio-incompatibility	Incompatibility between material and human body structure.
Incorrect output	Contains foreign substance or hair
incorrect formulation (chemical composition)	----
toxicity	Product material or packaging materials cause toxicity.
allergenicity	Product material or packaging materials cause allergic reaction.
mutagenicity	----
teratogenicity	----
oncogenicity	----
carcinogenicity	----
re-and/or cross-infection	----
pyrogenicity	----
inability to maintain hygienic safety	----
degradation	----

Environmental hazards and contributory factors	**Reasons**
electromagnetic fields	----
susceptibility to electromagnetic interference	----
emissions of electromagnetic interference	----
inadequate supply of power	----
inadequate supply of coolant	----
storage or operation outside prescribed environmental conditions	The device degraded due to storage in hot, light or moist place.
incompatibility with other devices with which it is intended to be used	----
accidental mechanical damage	----
contamination due to waste products and/or medical device disposal	Contamination because the product hasn't been destroyed immediately after use

Hazards resulting from incorrect output of energy and substances	**Reasons**
electricity	----
radiation	----
volume	----
pressure	----
supply of medical gases	----
supply of anaesthetic agents	----

Hazards related to the use of the medical device and contributory factors	Reasons
inadequate labeling	Misuse led by incorrect information
inadequate specification of accessories to be used with the medical device	----
inadequate specification of pre-use checks	----
over-complicated instructions for use	----
inadequate specification of service and maintenance	----
use by unskilled/untrained personnel	----
reasonably foreseeable misuse	----
insufficient warning of side effects	Misuse led by incorrect description or extremely less information on the label.
inadequate warning of hazards likely with re-use of single-use medical devices	----
incorrect measurement and other metrological aspects	----
incompatibility with consumables/ accessories/ other medical devices	----
sharp edges or points	----

Inappropriate, inadequate or over-complicated user interface (man/machine communication)	**Reasons**
mistakes and judgement errors	----
lapses and cognitive recall errors	----
slips and blunders (mental or physical)	----
violation or abbreviation of instructions procedures, etc	----
complex or confusing control system	----
ambiguous or unclear device state	----
ambiguous or unclear presentation of settings, measurements or other information	----
misrepresentation of results	----
insufficient visibility, audibility or tactility	----
poor mapping of controls to action, or of displayed information to actual state	----
controversial modes or mappings as	----

compared to existing equipment	

Hazards arising from functional failure, maintenance and ageing and contributory factors	**Reasons**
Erroneous data transfer	Infection due to use of expiry date exceeded product
lack of, or inadequate specification for maintenance including inadequate specification of post-maintenance functional checks	----
inadequate maintenance	----
lack of adequate determination of the end of life of the medical device	No specific period of validity or incorrect stipulation of service life
loss of electrical/mechanical integrity	Packing damage, Product damage
inadequate packaging (contamination and/or deterioration of the medical device)	The seal of packaging is bad.
re-use and/or improper re-use	Reuse of product for single use
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.	---

6.2. Determination on known and foreseeable hazards

Determinations of the group on relative potential hazards are as following:

H1. Bacterial infection: due to halfway sterilize or damaged packaging

H2.Unqualified Bio-compatibility cause allergic reaction, toxicosis: material or packaging material is not medical class

H3. Baneful chemical matter included: material or packaging material is not medical class

H4. Use the Medical isolation gown on other conditions which is not its indications.

H5.Packing bags are damaged

H6. Contamination or deterioration.

H7. Products that are beyond expiry date may be used.

H8. Repeated use: incorrect use or improper guidance led by inadequate or error of labeling or attention items

H9. Wrong specification

H10. Unqualified process control on process of materials mixing, defoaming, dipping, drying.

H11. Bad performance such as Resistance to microbial penetration, Cleanliness, Linting, Bursting strength, Tensile strength.

H12. Unreasonable disposal.

H13. Production lot number can not be traced.

H14. Mixture of different specifications.

H15. Unqualified materials such as PP+PE, PP, SMS, PE, .

H16. Stains in the Medical isolation gown.
H17. Inadequate information provided to users.
H18. Breakage of Medical isolation gown
H19. Shipping problem
H20 Hair inside cause pollution of product
H21 Allergic reaction to users

7. Risk control

7.1 All measures

M1.Strictly control incoming materials cleanness
M2. Choose qualified packaging materials
M3.Strictly control packaging process
M4.Perform effective packaging monitoring
M5.Monitor and measure the working environment
M6.Strictly evaluate the supplier
M7.Select raw material and packaging materials for medical use
M8.Perform process validation on materials mixing, defoaming, dipping, drying.
M9.Strictly control production process and working environment
M10.Strictly control the incoming products quality
M11. Pay attention to products protection in transport and storage
M12. Keep warehouse ventilating and dry and clean, stow products orderly, handle with care to guard against breakage
M13.Stack shall not be too high.
M14.Use caution in label
M15. Mention product validity in the label
M16. Strictly In-process control and finished product inspection.
M17. Strict on-site management
M18. In-process inspection of process parameters.
M19. Strictly conduct identification and traceability in production.
M20. Reasonable settlement of different materials and lot products in the warehouse.
M21. Design label and write instruction for use according to ISO standards
M22. Design appropriately the product package;
M23. In-process inspection on packaging of device.
M24 Clearly define the use indication for the product.
M25 Strictly In-process control and finished product inspection for package
M26 Choose medical class materials;
M27 Control production environment

7.2 Risk control form

7.2.1 Severity level S

1= Neglectable
2= Minor
3= Serious
4= Critical

5=Catastrophic

7.2.2 Probability of occurrence P

1= Improbable

2= Remote

3= Occasional

4= Probable

5= Frequent

7.2.3 Cause of the risk will be marked with "C" while control measures of the risk will be marked with "M".

Risk control form see Appendix A.

8. Result of risk control

As showing in the following risk control form, the residual risks of each hazard/cause have been reduced to acceptable range. It is visible that there are 21 conditions when no control measures have been taken. While no unacceptable condition will exist after taking relevant control measures, and the residual 21 conditions are all kept in acceptable range.

No relevant measures have been taken

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)					
Probable (P4)					
Occasional (P3)			18		
Remote (P2)			1	2	
Improbable (P1)					

Relevant measures have been taken

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)					
Probable (P4)					
Occasional (P3)					
Remote (P2)					
Improbable (P1)			19	2	

Therefore, total amount of residual individual risk may also be regarded as acceptable.

9. Requirements of MDD on risk management

According to Annex ZA of EN ISO 14971:2012, the risk management shall consider requirement of MDD 93/42/EEC. There are 7 points required during risk management. Following is instruction of this risk management report on the 7 points:

9.1 Treatment of negligible risks:

In this risk management report, all negligible risk are considered and taken measure to reduce its risk as much as possible.

9.2 Discretionary power of manufacturers as to the acceptability of risks:

In this risk management report, all acceptable risks are taken measure to reduce its risk as much as possible.

9.3 Risk reduction "as far as possible" versus "as low as reasonably practicable"

In this risk management report, all risks are divided into only two levels: Acceptable, and Unacceptable, the two levels all shall be taken measures to reduce its risks, no U was used.

9.4 Discretion as to whether a risk-benefit analysis needs to take place:

In this risk management report, overall risk-benefit analysis will be taken on chapter 9.

See chapter 9 of the risk management report.

9.5 Discretion as to the risk control options/measures:

In this risk management report, all control options related to general acknowledged state of the art and the most appropriate solutions were considered during risk management.

9.6 Deviation as to the first risk control option:

During conducting risk control for the device, the company as far as possible to use design and construction to reduce the risks.

9.7 Information of the users influencing the residual risk:

In this risk management report, instruction for use only as a auxiliary information for operation caution, intended use, contraindication etc., not as a measure to reduce risk additionally.

10. The evaluation of synthetic residual risk

After our company taking measures to reduce risk, unacceptable hazards have dropped to an acceptable level of risk. After taking measures to reduce risk, no one generated new risks. After confirmed by the panel of judges that the product’s overall residual risk is acceptable.

Detail evaluation:

1) Is there with individual risk after risk control?

Conclusion: conflicting requirements exist now.

2) Review of warning

Conclusion: No warning

3) Review of Label

Conclusion: Label meet the provision of EN ISO 15223-1, and description of product safety is clear and understandable, easy to read.

4) Compared with similar products

No need clinical validation.

5) Expert conclusion

Conclusion: after analyzing the above aspects, the risk management review panel made comprehensive communication with clinical application specialists; finally they agreed on that this product's overall residual risk is acceptable.

9. Production and post-production information

There are no customer feedback of the Medical isolation gown.

10. Conclusion

As displayed the risk analysis, all risks are under control and kept in lower part of R range or acceptable range, safety of the medical device has been adequately stipulated, summing up all the above, we think the risks are all under control and be acceptable. When new documents and data are used, the new round of risk analysis shall be carried out, for example, along with time passing, the risk may change and production process and product structure may be change accordingly. New risk may occurs or to be determined for the first time

Category	Potential Risk	Causes	Before taking control measures			Control measures	Applied standard & document	New risk	Residual risk		
			S	P	R				S	P	R
Design , purchase, and production	H1. Bacterial infection	C1.1 Bacteria contains in the product C1.2 Package was broken	S3	P3	U	M1.Strictly control incoming materials cleanness M2. Choose qualified packaging materials M3. Strictly control packaging process M4.Perform effective packaging monitoring M5.Monitor and measure the working environment	1..Product Surveillance and Measurement Management procedure 2.Packaging record 3. Inspection report for clean room	No	S3	P1	A
	H2.Unqualified Biocompatibility cause allergic reaction, toxicosis	C2 Products/Packing material is not medical class	S3	P3	U	M6.Strictly evaluate the supplier M7.Select raw materials and packing materials for medical use	1.Supplier evaluation Procedures 2.Product Surveillance and Measurement Management procedure 3.Biocompatibility reports	No	S3	P1	A
	H3.Baneful chemical matter	C3 Products/Packing material is poisonous	S3	P2	A	M6.Strictly evaluate supplier M7.Select raw materials and packing materials for medical use	1.Supplier evaluation Procedures 2.Product Surveillance and Measurement Management procedure 3.Products/Packing raw material test report	No	S3	P1	A
	H4. Use the Medical isolation gown on other conditions which is not its indications	Misuse of the Medical isolation gown	S3	P3	U	M24 Clearly define the use indication for the product.	Instruction for use (IFU-XTDC03)	No	S3	P1	A
Design , purchase, and production	H5.Packing bags are damaged	C5.1 Packing material is unqualified C5.2Mistake transport and storage	S3	P3	U	M7.Select suitable packing material M11 Pay attention to products protection in transport and storage	1.Quality agreement with supplier 2. Agreement with shipping firm. 3. Packing raw material test report	No	S3	P1	A
	H6.Contamination or deterioration	C6 The seal of packaging can't meet requirements	S3	P3	U	M3.Strictly control packing process M12 Keep warehouse ventilating and dry, stow products orderly, handle with care to guard against breakage.	1.Product Surveillance and Measurement Management procedure 2. Packing validation report	No	S3	P1	A
	H7.Deformation of products	C7 Improper loading during transportation	S3	P3	U	M13Stack shall not be too high M12Carton shall be made from	1. Agreement with shipping firm 2. Materials requirement in technical	No	S3	P1	A

						corrugated paper	documents				
	H8. Products that are beyond expiry date may be used.	C8 Incorrect operation of medical care personnel	S3	P3	U	M15. Mention product validity in the label M3.Strictly control packaging process	Label of Medical isolation gown Packaging inspection SOP	No	S3	P1	A
	H9. Wrong specification	C9.1 Wrong Medical isolation gown mold used C9.2 Wrong package during the packaging process, in result, wrong specification is used during operation	S3	P3	U	M16. Strictly In-process control and finished product inspection. M18. In-process inspection of process parameters.	1. In-process inspection and monitoring records. 2. In-process parameter monitoring record of injecting machine	No	S3	P1	A
	H10. Unqualified process control on process of materials mixing, defoaming, dipping, drying.	C11.1 Wrong process parameter during manufacture. C11.2 Wrong operation without following SOP requirement C11.3 Unqualified materials	S3	P3	U	M8.perform process validation on materials mixing, defoaming, dipping, dryingM 16. Strictly In-process control and finished product inspection. M18. In-process inspection of process parameters.	1. In-process inspection and monitoring records. 2. In-process parameter monitoring record of injecting machine, ultrasonic machine 3. Validation report of materials mixing, defoaming, dipping, drying.	No	S3	P1	A
	H11. Bad performance such as Resistance to microbial penetration, Cleanliness, Linting, Bursting strength, Tensile strength	C11.1 Wrong process parameter during manufacture. C11.2 Wrong operation without following SOP requirement C11.3 Unqualified materials	S3	P3	U	M6.Strictly evaluate the supplier M10.Strictly control the incoming products quality M16. Strictly In-process control and finished product inspection. M18. In-process inspection of process parameters.	1. In-process inspection and monitoring records. 2. In-process parameter monitoring record of injecting machine, ultrasonic machine 3. Incoming materials inspection records	No	S3	P1	A
	H12. Unreasonable disposal.	C12 No caution to users	S3	P3	U	M14. Use catuion in label M3.Strictly control packaging process	Label of Medical isolation gown Packaging inspection SOP	No	S3	P1	A
	H13 Production lot number can not be traced.	C13.1 Failure of product identification and traceability in manufacture process. C13.2 Wrong package during the packaging process, in result, wrong LOT information is used during operation	S3	P3	U	M16. Strictly In-process control and finished product inspection. M17. Strict on-site management	1. In-process inspection and monitoring records. 2.On-site inspection	No	S3	P1	A
	H14. Mixture of different specifications.	C14.1 mixture during package process. C14.2 wrong settlement in the warehouse	S4	P2	U	M17. Strict on-site management M20 Reasonable settlement of different materials and lot products in the warehouse.	1. In-process inspection and monitoring records. 2.On-site inspection	No	S4	P1	A
	H15. Unqualified materials such as PP+PE, PP, SMS,	C15.1 Unqualified materials from supplier	S4	P2	U	M6.Strictly evaluate the supplier M10.Strictly control the incoming	Supplier evaluation record Incoming materials inspection SOP	No	S4	P1	A

	PE,	C15.2 Unqualified incoming materials inspection control				products quality					
	H16. Stains in the Medical isolation gown	C11.1 Unqualified process control during manufacture. C11.3 Unqualified materials	S3	P3	U	M8.perform process validation on materials mixing, defoaming, dipping, drying M16. Strictly In-process control and finished product inspection. M18. In-process inspection of process parameters.	1. In-process inspection and monitoring records. 2. In-process parameter monitoring record of injecting machine, ultrasonic machine 3. Validation report of materials mixing, defoaming, dipping, drying.	No	S3	P1	A
	H17. Inadequate information provided to users.	C16. Inadequate information cause misuse of the device	S3	P3	U	M21. Design label and write instruction for use according to ISO standards M3.Strictly control packaging process	Label of Medical isolation gown Packaging inspection SOP	No	S3	P1	A
	H18. Breakage of Medical isolation gown	C18.1 Unqualified process control during manufacture. C18.2 Unqualified materials	S3	P3	U	M8.perform process validation on materials mixing, defoaming, dipping, drying M16. Strictly In-process control and finished product inspection. M18. In-process inspection of process parameters.	1. In-process inspection and monitoring records. 2. In-process parameter monitoring record of injecting machine, ultrasonic machine 3. Validation report of materials mixing, defoaming, dipping, drying.	No	S3	P1	A
	H19. Shipping problem	C19.1 Unqualified package design. C19.2 Unqualified process control during packaging	S3	P3	U	M22. Design appropriately the product package; M23. In-process inspection on packaging of device.	1. Package design specification 2. In-process inspection and monitoring records.	No	S3	P1	A
Hazards identified from PMS	H20 Hair inside cause pollution of product	C20 Unqualified package process	S3	P3	U	M25 Strictly In-process control and finished product inspection for package	In-process control and finished product inspection SOP	No	S3	P1	A
	H21 Allergic reaction to users	C21.1 Unqualified materials; C21.2 Unqualified environment control during manufacturing	S3	P3	U	M26 Choose medical class materials; M27 Control production environment	Materials test reports Bio-compatibility report of Medical isolation gown Environment control SOP	No	S3	P1	A

Design and Manufacturing Control

Company: XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD
Address: LIUKOU INDUSTRIAL PARK, XIANTAO CITY, HUBEI PROVINCE, CHINA

Document History Summary

No	Summary of Changes	Effective Date	Version
1	New established	2020-05-06	A/0

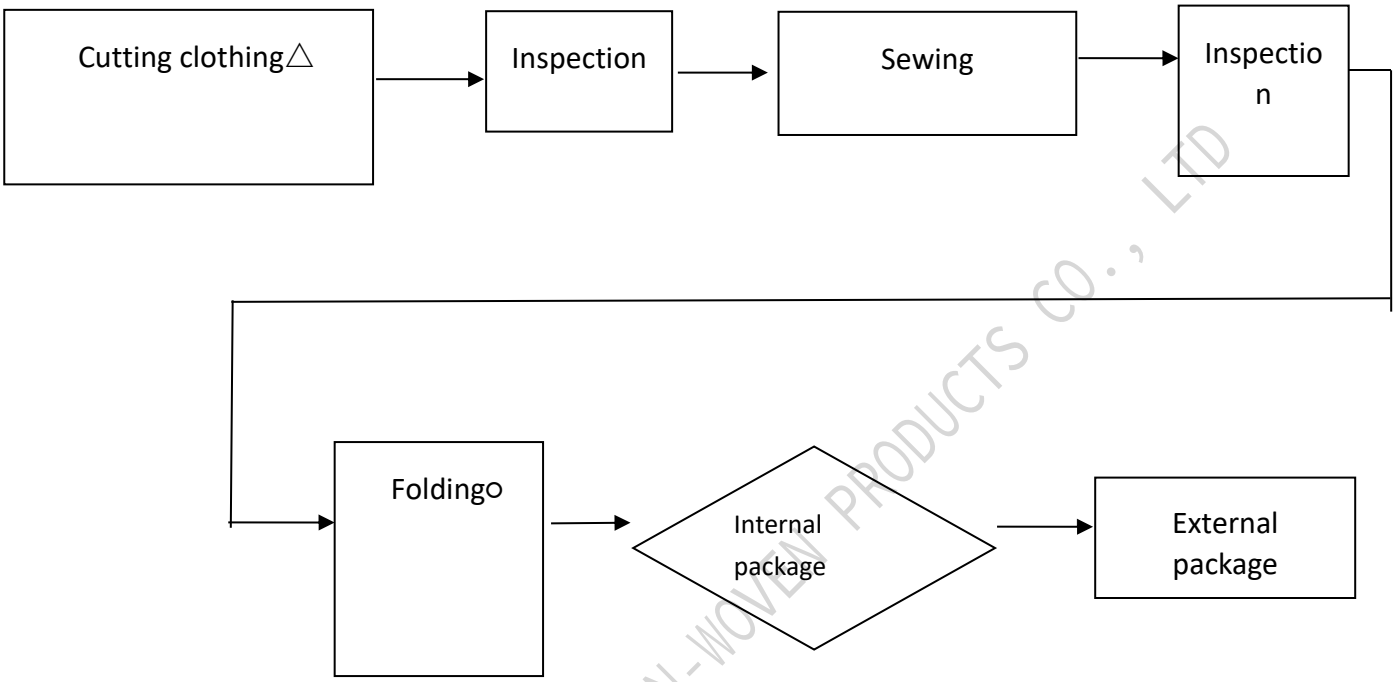
1. Design flowchart

The company implement the design of glove based on ISO 13485 section 7.3, and applied other regulations and standards.

The design flow follows Design plan, Design input, Design output, Design review, Design verification, Design validation, Design transfer defined in ISO 13485 section 7.3. These design records as follows:

Design stages	Design records
Design plan	6) R&D advice; 7) Product project application; 8) R&D task; 9) R&D plan); 10) R&D plan review report;
Design input	4) Design input sheet; 5) Design input accessories; 6) Risk management plan;
Design output and review	4) Design output sheet; 5) R&D output review report; 6) Risk management report;
Design verification and validation	5) Trial production report; 6) Process validation plan; 7) R&D verification report; 8) R&D validation report ;
Design transfer	R&D transfer report.

2. Flowchart of manufacturing



Production and quality control process

- Picking: cutting workshop to warehouse to pick up fabric.
- Cutting: cut the fabric into pieces according to the pattern.
  - three-wire machine: using the three-wire machine edge-cuff technology to close the sleeve
  - Collar: Wrap the collar up with a flat machine's curving process.
  - Upper Lumbar Belt: Roll 2.5 cm strips of cloth of the same color as cm garment into a 0.6 cm~0.8 belt using a flat machine; then cut them to 171 cm±5 cm long by the operator; Center the belt up to the clothing location, the two ends of the location must be hit back.
- Folding :
  - 1. check the shape and appearance of each garment first, then put the back of the garment up flat and shoulder flat.
  - 2. Fold sleeve inward along the sleeve, place the middle of the sleeve, and fold the belt inward.
  - 3. fold the left and right sides of the garment inward along the collar to give it a long coat of 23 cm±1 cm.
  - 4. fanned the clothes up from the bottom twice.
- Packaging:
  - 1. put 10 pieces of clothes in a bag.
  - 2. Pack 10 bags of clothes in a box and seal the box with a seal belt.
- Storage: put the products that have been packed into storage.

Usability Evaluation

According to

EN 62366-1:2015+AC:2015: Medical device software. Software life-cycle processes

Report Reference No.....:	XTDC/CE03-01-04(A/0)
Date of issue..... :	2020-05-06
Total number of pages.....	10
Manufacturer's name..... :	XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD
Address..... :	LIUKOU INDUSTRIAL PARK, XIANTAO CITY, HUBEI PROVINCE, CHINA
Evaluation specification:	
Standard..... :	EN 62366-1:2015+AC:2015
Trade Mark.....:	
Product name..... :	Medical isolation gown
Model/Type reference..... :	PP+PE, PP, SMS, PE
Ratings..... :	

Evaluated by (+ signature).....:	Wang Manzhen			
Reviewed by (+ signature)	Du Jianmin			
Approved by (+ signature).....:	Cheng Qin			
Evaluation procedure: TMP				
Evaluation location/ address:	LIUKOU INDUSTRIAL PARK, XIANTAO CITY, HUBEI PROVINCE, CHINA			

Evaluation item particulars..... :			
Classification of installation and use.....:			
Supply connection .....:			
Context of Use .....:			
Abbreviations used in the report:			
- Usability Engineering:	UE	- Risk analysis:	RA
- User interface:	UI	- Risk management:	RM
- Primary operating function:	POF		
Possible test case verdicts:			
- evaluation case does not apply to the test object.....:	N.A		
- evaluation object does meet the requirement..... :	Pass (P)		
- evaluation object does not meet the requirement..... :	Fail (F)		
General remarks:			
The evaluation results presented in this report relate only to the object evaluated. This report shall not be reproduced, except in full, without the written approval of the Issuing evaluation". Throughout this report, a point (coma) is used as the decimal separator. **This Evaluation Report contains the general safety requirements as related to the usability of Medical Equipment.**			
General product information: **Product name:** Medical isolation gown **Intended use:** The medical device is intended to be worn by healthcare providers or visitors to isolate themselves from patients, helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Single-use, Non-sterile.			

Clause	Requirement + Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		
4.1	General Requirements		
4.1.1	USABILITY ENGINEERING PROCESS		P
	Has the MANUFACTURER established, documented and maintained a USABILITY ENGINEERING PROCESS to provide SAFETY for the PATIENT, USER and others related to USABILITY for the product?	In the ISO13485 QMS, "Product R&D control procedure" has clarify the usability engineering process for the product.	P
	Does the PROCESS addressed USER INTERACtions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?	The label(Label-XTDC03) and Instruction for use (IFU-XTDC03) of the product fully provide these information.	P
4.1.2	RISK CONTROL as it relates to USER INTERFACE design		
	TO REDUCE USE-RELATED RISK, THE MANUFACTURER SHALL USE ONE OR MORE OF THE FOLLOWING OPTIONS, IN THE PRIORITY LISTED (AS REQUIRED BY ISO 14971:2007, 6.2): A) INHERENT SAFETY BY DESIGN; B) PROTECTIVE MEASURES IN THE MEDICAL DEVICE ITSELF OR IN THE MANUFACTURING PROCESS; C) INFORMATION FOR SAFETY.	Risk assessment was conducted according to EN ISO 14971:2012, and residual risk was under acceptable level. (Risk analysis report XTDC/CE03-01-07 XTDC/CE03-01-07)	P
4.1.3	Information for Safety as it relates to USABILITY		
	INFORMATION FOR SAFETY USED AS A RISK CONTROL MEASURE HAS BEEN EVALUATED ACCORDING TO THE USABILITY ENGINEERING PROCESS TO DETERMINE THAT THE INFORMATION -IS PERCEIVABLE BY -IS UNDERSTANDABLE TO, AND -SUPPORTS CORRECT USE OF THE MEDICAL DEVICE BY USERS OF THE INTENDED USER PROFILES IN THE CONTEXT OF THE INTENDED USE ENVIRONMEN	Safety information was considered in the risk assessment. (Risk analysis report XTDC/CE03-01-07 XTDC/CE03-01-07)	P
	Disregarding such information for SAFETY is considered beyond any further reasonable means of RISK CONTROL	No disregarding such information.	N.A
4.2	THE RESULTS OF THE USABILITY ENGINEERING PROCESS ARE STORED IN THE USABILITY ENGINEERING FILE :		
	THE RESULTS OF THE USABILITY ENGINEERING PROCESS SHALL BE STORED IN THE USABILITY ENGINEERING FILE. THE RECORDS AND OTHER DOCUMENTS THAT FORM THE USABILITY ENGINEERING FILE MAY FORM PART OF OTHER DOCUMENTS AND FILES.	Product design files according to requirements of ISO13485:2003 and EN 62366-1:2015+AC:2015.	P
4.3	TAILORING OF THE USABILITY ENGINEERING EFFORT		

Clause	Requirement + Test	Result - Remark	Verdict
	The level of effort and the choice of methods and tools used to perform the USABILITY ENGINEERING PROCESS may vary based on: a) the size and COMPLEXITY of the USER INTERFACE; b) the SEVERITY of the HARM associated with the use of the MEDICAL DEVICE; c) the extent or complexity of the USE SPECIFICATION; d) the presence of USER INTERFACE OF UNKNOWN PROVENANCE; and e) the extent of the modification to an existing MEDICAL DEVICE USER INTERFACE that had been subjected to the USABILITY ENGINEERING PROCESS.	The usability engineering process was considered in full R&D process of this product	P
5	USABILTY ENGINEERING PROCESS		P
5.1	Prepare USE SPECIFICATION		
	The MANUFACTURER shall prepare a USE SPECIFICATION. The USE SPECIFICATION shall include: – * intended medical indication; – intended PATIENT population; – intended part of the body or type of tissue applied to or interacted with; – * intended USER PROFILE; – * USE ENVIRONMENT; and – * operating principle.	For all kinds of patients use, and warning information was included in the instruction for use (IFU-XTDC03) Usability specification	P
5.2	Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS		P
	The MANUFACTURER shall identify USER INTERFACE characteristics that could be related to SAFETY as part of a RISK ANALYSIS performed according to ISO 14971:2007, 4.2. This identification may also be performed using the tools and techniques from the USABILITY ENGINEERING PROCESS. This identification shall include consideration of the PRIMARY OPERATING FUNCTIONS that are provided in applicable particular MEDICAL DEVICE SAFETY standards.	R&D records described these requirements. Usability specification	P
	Based on the identified USER INTERFACE characteristics and USE SPECIFICATION, the MANUFACTURER shall identify the USE ERRORS that could occur and are related to the USER INTERFACE	For all kinds of patients use, and warning information was included in the instruction for use (IFU-XTDC03) Usability specification	P
5.3	IDENTIFY KNOWN OR FORESEEABLE HAZARDS AND HAZARDOUS SITUATIONS		

Clause	Requirement + Test	Result - Remark	Verdict
	THE MANUFACTURER SHALL IDENTIFY KNOWN OR FORESEEABLE HAZARDS AND HAZARDOUS SITUATIONS, WHICH COULD AFFECT PATIENTS, USERS OR OTHERS, RELATED TO USE OF THE MEDICAL DEVICE. THIS IDENTIFICATION SHALL BE CONDUCTED AS PART OF A RISK ANALYSIS PERFORMED ACCORDING TO ISO 14971:2007, 4.3 AND THE FIRST PARAGRAPH OF ISO 14971:2007, 4.4.	Identification of characteristics related to safety was performed in the risk assessment report Usability specification	P
	During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following shall be considered: – USE SPECIFICATION, including USER PROFILE(S) (see 5.1); – information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; and – identified USE ERRORS	These characteristics were considered during in the risk assessment report Usability specification	P
	The results of this identification of HAZARDS and HAZARDOUS SITUATIONS shall be stored in the USABILITY ENGINEERING FILE.	It is in compliance with the requirements, Usability specification	P
5.4	Identify and describe HAZARD-RELATED USE SCENARIOS		
	The MANUFACTURER shall identify and describe the reasonably foreseeable HAZARD-RELATED USE SCENARIOS associated with the identified HAZARDS and HAZARDOUS SITUATIONS. The description of each identified HAZARD-RELATED USE SCENARIO shall include all TASKS and their sequences as well as the SEVERITY of the associated HARM.	The operating functions were described in Instruction, and product description in CE technical files (RN/CE-01)	P
5.5	Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION		
	The MANUFACTURER shall select the HAZARD-RELATED USE SCENARIOS to be included in the SUMMATIVE EVALUATION.	These information was included	P
	The MANUFACTURER shall select either: – all HAZARD-RELATED USE SCENARIOS; or – the subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM that could be caused by USE ERROR (e.g. for which medical intervention would be needed).	These information was included, Usability specification	P

Clause	Requirement + Test	Result - Remark	Verdict
	The choice of the scheme used to select the HAZARD-RELATED USE SCENARIOS may additionally depend on other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER.	These information was included, Usability specification	P
	A summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the USABILITY ENGINEERING FILE.	These information was described, Usability specification	P
5.6	Establish USER INTERFACE SPECIFICATION		P
	The MANUFACTURER shall establish and maintain a USER INTERFACE SPECIFICATION. The USER INTERFACE SPECIFICATION shall consider: – the USE SPECIFICATION (see 5.1); – the known or foreseeable USE ERRORS associated with the MEDICAL DEVICE (see 5.2); and – the HAZARD-RELATED USE SCENARIOS (see 5.4).	Usability validation plan was considered during R&D, Usability specification	P
	The USER INTERFACE SPECIFICATION shall include: – testable technical requirements relevant to the USER INTERFACE, including the requirements for those parts of the USER INTERFACE associated with the selected RISK CONTROL measures; – an indication as to whether ACCOMPANYING DOCUMENTATION is required; and – an indication as to whether MEDICAL DEVICE-specific training is required.	Risk management report Design and development data Instruction for use (IFU-XTDC03), Usability specification	P
	The USER INTERFACE SPECIFICATION shall be stored in the USABILITY ENGINEERING FILE. The USER INTERFACE SPECIFICATION may be integrated into other specifications.	Design and development data Instruction for use (IFU-XTDC03) , Usability specification	P
5.7	Establish USER INTERFACE EVALUATION plan		P
	MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION utilizing, as appropriate, USABILITY ENGINEERING methods and techniques	Usability verification plan	P
	THE MANUFACTURER SHALL ESTABLISH AND MAINTAIN A USER INTERFACE EVALUATION PLAN FOR THE USER INTERFACE SPECIFICATION.	Usability verification plan	P
	THE USER INTERFACE EVALUATION PLAN SHALL A) DOCUMENT THE OBJECTIVE AND IDENTIFY THE METHOD OF ANY PLANNED FORMATIVE EVALUATIONS AND SUMMATIVE EVALUATIONS;	Usability verification plan	P

Clause	Requirement + Test	Result - Remark	Verdict
	B) IF USABILITY TESTS ARE EMPLOYED, – DOCUMENT THE INVOLVEMENT OF THE REPRESENTATIVE INTENDED USERS AND USER PROFILE TO WHICH THEY BELONG	Usability verification plan	P
	USER INTERFACE EVALUATION METHODS MAY BE QUANTITATIVE OR QUALITATIVE. USER INTERFACE EVALUATION MAY BE PERFORMED IN A VARIETY OF LOCATIONS, SUCH AS, IN A LABORATORY SETTING, IN A SIMULATED USE ENVIRONMENT OR IN THE ACTUAL USE ENVIRONMENT	Usability verification plan	P
5.7.2	THE USER INTERFACE EVALUATION PLAN FOR FORMATIVE EVALUATION SHALL ADDRESS: A) THE EVALUATION METHODS BEING USED; B) WHICH PART OF THE USER INTERFACE IS BEING EVALUATED; AND C) WHEN IN THE USABILITY ENGINEERING PROCESS TO PERFORM EACH OF THE USER INTERFACE EVALUATIONS.	Usability verification plan	P
5.7.3	FOR EACH SELECTED HAZARD-RELATED USE SCENARIO (SEE 5.5), THE USER INTERFACE EVALUATION PLAN FOR SUMMATIVE EVALUATION SHALL SPECIFY: A) THE EVALUATION METHOD BEING USED AND A RATIONALE THAT THE METHOD PRODUCES OBJECTIVE EVIDENCE; B) WHICH PART OF THE USER INTERFACE IS BEING EVALUATED; C) WHERE APPLICABLE, THE CRITERIA FOR DETERMINING WHETHER THE INFORMATION FOR SAFETY IS PERCEIVABLE, UNDERSTANDABLE AND SUPPORTS CORRECT USE OF THE MEDICAL DEVICE (4.1.3) D) * THE AVAILABILITY OF THE ACCOMPANYING DOCUMENTATION AND PROVISION OF TRAINING DURING THE SUMMATIVE EVALUATION; AND E) * FOR A USABILITY TEST, – THE TEST ENVIRONMENT AND CONDITIONS OF USE AND A RATIONALE FOR HOW THEY ARE ADEQUATELY REPRESENTATIVE OF THE ACTUAL CONDITIONS OF USE; AND – THE METHOD OF COLLECTING DATA DURING THE USABILITY TEST FOR THE SUBSEQUENT ANALYSIS OF OBSERVED USE ERRORS.	Usability verification plan	P
5.8	THE MANUFACTURER SHALL DESIGN AND IMPLEMENT THE USER INTERFACE, INCLUDING THE ACCOMPANYING DOCUMENTATION IF NEEDED, AND TRAINING CAPABILITY, IF NEEDED, AS DESCRIBED IN THE USER INTERFACE SPECIFICATION.	Usability verification plan	P

Clause	Requirement + Test	Result - Remark	Verdict
	THE MANUFACTURER SHALL UTILIZE, AS APPROPRIATE, USABILITY ENGINEERING METHODS AND TECHNIQUES, INCLUDING FORMATIVE EVALUATION TO ACCOMPLISH THIS DESIGN AND IMPLEMENTATION. THE RESULTS OF THE UTILIZED FORMATIVE EVALUATION SHALL BE STORED IN THE USABILITY ENGINEERING FILE. WHERE NEW USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS OR HAZARD-RELATED USE SCENARIOS ARE DISCOVERED DURING THIS STEP, THE MANUFACTURER SHALL REPEAT THE STEPS OF CLAUSE 5 AS APPROPRIATE.	Usability verification plan	P
	IF TRAINING ON THE SPECIFIC MEDICAL DEVICE IS REQUIRED FOR THE SAFE USE OF THE MEDICAL DEVICE BY THE INTENDED USER, THE MANUFACTURER SHALL DESIGN AND IMPLEMENT A TRAINING CAPABILITY FOR THE EXPECTED SERVICE LIFE OF THE MEDICAL DEVICE BY DOING AT LEAST ONE OF THE FOLLOWING: – PROVIDE THE MATERIALS NECESSARY FOR TRAINING; – ENSURE THAT THE MATERIALS NECESSARY FOR TRAINING ARE AVAILABLE; – MAKE THE TRAINING AVAILABLE; OR – MAKE TRAINING AVAILABLE TO THE RESPONSIBLE ORGANIZATION THAT ENABLES IT TO TRAIN ITS USERS.	Usability verification plan	P
5.9	PERFORM SUMMATIVE EVALUATION OF THE USABILITY OF THE USER INTERFACE	-	-
	UPON COMPLETION OF THE DESIGN AND IMPLEMENTATION OF THE USER INTERFACE, THE MANUFACTURER SHALL PERFORM A SUMMATIVE EVALUATION OF EACH HAZARD-RELATED USE SCENARIO SELECTED IN 5.5 ON THE FINAL OR PRODUCTION EQUIVALENT USER INTERFACE ACCORDING TO THE USER INTERFACE EVALUATION PLAN. FOR SUMMATIVE EVALUATION, THE MANUFACTURER MAY USE DATA OBTAINED FROM THE SUMMATIVE EVALUATIONS OF PRODUCTS WITH AN EQUIVALENT USER INTERFACE TOGETHER WITH A TECHNICAL RATIONALE FOR HOW THIS DATA IS APPLICABLE. THE RESULTS SHALL BE STORED IN THE USABILITY ENGINEERING FILE.	DESIGN AND DEVELOPMENT DATA Risk management report USABILITY VERIFICATION RECORD , USABILITY VERIFICATION REPORT	P

Clause	Requirement + Test	Result - Remark	Verdict
	THE DATA FROM THE SUMMATIVE EVALUATION SHALL BE ANALYSED TO IDENTIFY THE POTENTIAL CONSEQUENCES OF ALL USE ERRORS THAT OCCURRED. IF THE CONSEQUENCES CAN BE LINKED TO A HAZARDOUS SITUATION, THE ROOT CAUSE OF EACH USE ERROR SHALL BE DETERMINED. THE ROOT CAUSES SHOULD BE DETERMINED BASED ON OBSERVATIONS OF USER PERFORMANCE AND SUBJECTIVE COMMENTS FROM THE USER RELATED TO THAT PERFORMANCE.	DESIGN AND DEVELOPMENT DATA Risk management report USABILITY VERIFICATION RECORD , USABILITY VERIFICATION REPORT	P
	IF NEW USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS OR HAZARD-RELATED USE SCENARIOS ARE DISCOVERED DURING THIS DATA ANALYSIS: – IF YES, THEN THE MANUFACTURER SHALL REPEAT THE ACTIVITIES OF CLAUSE 5 AS APPROPRIATE; – IF NOT, THE MANUFACTURER SHALL DETERMINE WHETHER FURTHER IMPROVEMENT OF THE USER INTERFACE DESIGN AS IT RELATES TO SAFETY IS NECESSARY AND PRACTICABLE.	DESIGN AND DEVELOPMENT DATA Risk management report USABILITY VERIFICATION RECORD , USABILITY VERIFICATION REPORT	P
	IF THE USABILITY ENGINEERING PROCESS DETAILED IN THIS INTERNATIONAL STANDARD HAS BEEN COMPLIED WITH, THEN THE USABILITY OF A MEDICAL DEVICE AS IT RELATES TO SAFETY IS PRESUMED TO BE ACCEPTABLE, UNLESS THERE IS OBJECTIVE EVIDENCE TO THE CONTRARY.	DESIGN AND DEVELOPMENT DATA Risk management report USABILITY VERIFICATION RECORD , USABILITY VERIFICATION REPORT	P
	COMPLIANCE IS CHECKED BY INSPECTION OF THE USABILITY ENGINEERING FILE AND BY APPLICATION OF THE REQUIREMENTS OF ISO 14971:2007, 6.4.	DESIGN AND DEVELOPMENT DATA Risk management report USABILITY VERIFICATION RECORD , USABILITY VERIFICATION REPORT	P
5.10	USER INTERFACE OF UNKNOWN PROVENANCE	NO DISREGARDING SUCH INFORMATION	N.A

Benefit-Risk analysis report

XTDC/CE03-01-07

Compiled by:	Wang Manzhen	Date:	2020-05-06
Reviewed by:	Du Jianmin	Date:	2020-05-06
Approved by:	Cheng Qin	Date:	2020-05-06

Company: XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD
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Document History Summary

No	Summary of Changes	Effective Date	Version
1	New established	2020-05-06	A/0

1. Summary

Medical isolation gown is a designed and manufactured product by XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD the product has not been sold to markets including EU.

This document is to analyze the device's benefit-risk based on requirements defined in MDR and MDCG 2019-15 Guidance notes for manufacturers of class I medical devices.

Through the analysis, the Medical isolation gown is proved that its benefit is widely higher than its risks when using the device for its intended use.

2. Introduction of device

Intend use of device:
The medical device is intended to be worn by healthcare providers or visitors to isolate themselves from patients, helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Single-use, Non-sterile.
Contraindications:
Users who is allergic to PP+PE, PP, SMS, PE materials.
Specifications: PP+PE, PP, SMS, PE
Validity of Medical isolation gown: 3 years.
GMDN code: 35492
UMDN code: 15037
Use cautions:
a. Keep the product properly to maintain its clean and avoid high temperature, high humidity and direct sun。
b. The product is for single use only. Please recycle or burn the product after using and don't litter.

3. Evaluation of the device's benefits to the patient

To conduct quantification evaluation of the device's benefits to the patient through four factors: Type of benefits, Probability of the patient experiencing benefits, Extent of benefits, and Duration of effect.

3.1 Factors of benefits

Benefit factors	Description
Type of benefits	Benefits may include a positive impact on clinical outcomes; the patient's quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or public health impact. For diagnosis device, It can identify specific diseases and thus prevent the spread of diseases, predict the occurrence of diseases in the future, provide early diagnosis of diseases, or identify patients who are more likely to benefit from the given treatment.
Extent of benefits	According to the specific evaluation endpoint or whether the evaluation has reached the predetermined health threshold, we can evaluate the benefits of patients by evaluating the change, endpoint improvement or deterioration, participants' health situation change, etc. At the same time, the change of the benefit the extent of different groups should be considered.
Probability of the patient experiencing benefits	Based on the data provided, it is possible to predict which patients will benefit. Data may indicate that only a small proportion of patients in the target population benefit, or that some benefit often occurs in the whole target population. Besides, it is also possible that different subgroups of patients have different benefits or different degrees of the same kind of benefits. When weighing benefits and risks, the extent and probability of benefits and risks should be considered at the same time. Compared with the majority of participants getting small benefits, the small number of participants getting large benefits may lead to different judgment results. For example, for a large benefit, even if only a few people benefit, it can be determined that the benefit is greater than the risk; for a small benefit, unless there are many beneficiaries, it cannot be determined that the benefit is greater than the risk.
Duration of effect	Some treatments are curative; some need long-term repeated treatment. Generally, the duration of treatment effect may directly affect the determination of its benefits. Treatment that must be

	repeated over a long period may introduce a greater risk, or the benefits may diminish as the treatment is repeated. For the diagnosis device, the diagnosis is normally for one-time use; no repeated diagnosis needed.

3.2 Classification criteria of evaluation factors

1) Types of benefits and Extent of benefits.

We choose Criteria (types of benefits) as factor to evaluate benefit, benefits may includes: positive impact on clinical outcome; the patient's quality of life; outcomes related to diagnosis; positive impact from diagnostic devices on clinical outcomes, or public health impact.

For the product of Medical isolation gown, it is not for diagnosis purpose, therefore, we choose positive impact on clinical outcome; the patient's quality of life as classification criteria.

	Class levels	Classification criteria
Type of benefits	B5	Obviously positive impact on clinical outcome, significant improvement of patient’s quality of life.
	B4	Obviously positive impact on clinical outcome, normal improvement of patient’s quality of life.
	B3	Normal positive impact on clinical outcome, normal improvement of patient’s quality of life; or Obviously positive impact on clinical outcome, while low improvement of patient’s quality of life.
	B2	Normal positive impact on clinical outcome, low improvement of patient’s quality of life; or Low positive impact on clinical outcome, while normal improvement of patient’s quality of life.
	B1	Low positive impact on clinical outcome, low improvement of patient’s quality of life.

2) Probability of the patient experiencing benefits

To classify probability of the patient experiencing one or more benefit according to magnitude and probability
of clinical benefits.

	Class levels	Classification criteria

Probability of the patient experiencing benefits	P5	Benefit almost occur in each patient in the target population.
	P4	Benefit occur frequently in patients throughout the target population.
	P3	Benefit experienced in middle proportion of patients in the target population.
	P2	Benefit experienced in small proportion of patients in the target population but there is clear subgroup.
	P1	Benefit experienced in small proportion of patients in the target population and there is not clear subgroup.

3) Duration of effect

To classify duration of effect of benefits according to treatment's repeated frequent.

	Class levels	Classification criteria
Duration of effect	D3	Treatments is curative, no need repeated again.
	D2	Several repeated treatment needed.
	D1	Frequently treatment needed.

3.3 Benefits acceptable criteria

There define three judgement level for benefit acceptable evaluation:

High benefit (H): the benefit is high;

Medium benefit (M): the benefit is medium;

Low benefit (L): the benefit is relative low.

The benefits shall be judged according to following criteria which comprehensively balance the Types of benefits, Probability of the patient experiencing benefits, and Duration of effect.

1) When Duration of effect is classified Level D3 (Table 1)

Types of benefits	Probability of the patient experiencing benefits (P)				
	P5	P4	P3	P2	P1
B1	M	L	L	L	L
B2	M	M	L	L	L
B3	M	M	M	M	L
B4	H	H	H	H	M
B5	H	H	H	H	H

2) When Duration of effect is classified Level D2 (Table 2)

Types of benefits	Probability of the patient experiencing benefits (P)				
	P5	P4	P3	P2	P1
B1	L	L	L	L	L
B2	M	L	L	L	L
B3	M	M	M	L	L
B4	H	H	H	M	M
B5	H	H	H	H	H

3) When Duration of effect is classified Level D1. (Table 3)

Types of benefits	Probability of the patient experiencing benefits (P)				
	P5	P4	P3	P2	P1
B1	L	L	L	L	L
B2	M	L	L	L	L
B3	M	M	M	L	L
B4	H	H	M	M	L
B5	H	H	H	M	M

3.4 Evaluation of device benefits

Benefit factors	Main concerning issues	Evaluation records	Supporting evidence	Classification
Type of benefits	a) What are the primary or alternative endpoints to be evaluated?	To protect the patient (e.g., burn patients) from the transfer of infectious agents carried by the health care provider or visitor	The intended use of the device is supported by Clinical evaluation report (XTDC/CE03-01-03)	B4
	b) What are the secondary or alternative endpoints evaluated?	To protect the health care provider or visitor from a contagious agent which has infected the patient.		
Extent of	a) For each primary endpoint	Effective for each	Product type test	

benefits	evaluated, and secondary endpoint or alternative endpoint: how effective is each treatment?	treatment	report Clinical evaluation report (XTDC/CE03-01-03)	
	b) How to measure benefits? According to the measurement method, what is the benefit?	Product test performance	Product type test report	
Probability of the patient experiencing benefits	a) Can this study predict which patients will benefit?	All users will benefit except who is allergic to non-woven materials	Clinical evaluation report (XTDC/CE03-01-03) Instruction for use (IFU-XTDCFV01)	P5
	b) What is the probability of benefits for patients expected to use?	100% users benefit		
	c) What are the differences in benefits between subgroups?	No difference		
	d) Are there differences in public health benefits among different groups of people?	No		
	e) Even if a small part of the total population benefits, how do these patients view the benefit value?	Very recognized		
Duration of effect	If repeated treatment needed?	Single use of product, it depend on use conditions for if use the Medical isolation gown many times	Instruction for use (IFU-XTDCFV01)	D2

According to above analyzed, according to Table 2 in section 3.3, the benefit is in the high level.

4. Evaluation of the clinical risks of devices

4.1 Factors on risks

For evaluation of risks on the device, we consider three factors:

Risks factors	Description

Clinical risks related to use of the product	To collect all clinical risks related to use of the product by risk analysis, clinical literature data, adverse events, etc. To analyze all identified clinical risks on severity, probability, take risk control measures, evaluate residual risks, and judge if residual risks acceptable.
Probability of adverse events	To evaluate probability of adverse events; and, Duration of adverse events risk.

4.2 Clinical risks identified of the product

Risk factors	Main concerning issues	Evaluation records	Related document
Clinical risks identified during design, production	19 risks identified in Risk management report	All 19 risks are decreased its risks to acceptable level after implementation of risk control measures, and all residual risks and synthetic risks are acceptable.	Risk management report
Adverse events	a) Adverse happen probability ?	Low probability which is less than 10^{-6}.	Risk management report
	b) Duration of adverse events risk?	Very short term	
Alternative method	If other effective alternative method for same intended use?	There are other alternative methods such as other type protective device, compared with them, the Medical isolation gown is easy to use, low cost, also effective.	Clinical evaluation report (XTDC/CE03-01-03)
	If the product is competitive than alternative methods		

5. Evaluation of acceptability of the benefit/risk profile

Medical isolation gown is a garment made of natural and/or synthetic materials intended to be worn by health care providers or visitors to isolate themselves from patients. The Medical isolation gown helps to protect the patient (e.g., burn patients) from the transfer of infectious agents carried by the health care provider or visitor; or it may help to protect the health care provider or visitor from a contagious agent which has infected the patient. This is a single-use garment. Its benefits for users is in the high level.

Considering that the risk control measures are clear and acceptable.According to a quantitative benefit evaluation in section 3, the benefits of the product are acceptable; according to risk evaluation in section 4 and Risk analysis report XTDC/CE03-01-07 , all identified risks are controlled to an acceptable level.

According to the evaluation of the device's intended purpose, the device’s benefits to the patient and clinical risks of devices during usage, consider nature, extent/severity, probability/frequency, duration of benefits to the patients and of undesirable side-effects and other risks. It can conclude that the benefits patients gained from this product are widely higher than its risks.

Clinical Evaluation Report

Compiled by:	Wang Manzhen	Date:	2020-05-06
Reviewed by:	Du Jianmin	Date:	2020-05-06
Approved by:	Cheng Qin	Date:	2020-05-06

1. Executive Summary

The Medical isolation gown is a disposable device intended for medical purposes that is worn on the examiner's hand or finger(s) to prevent contamination between patient and examiner.

The Medical isolation gown is designed for single use only, made of compounded SMS chloride paste resin, non-sterile product, beaded.

The Medical isolation gown uses its materials characteristics as physical protection barrier to separate infectious substance so as to prevent contamination between patient and examiner.

As the definition of medical device in MDR (EU) 2017/745 Article 2(1) , the Medical isolation gown is a defined as a medical device.

For the device of Medical isolation gown, the company implement this clinical evaluation based on Article 61 (10) of MDR (EU) 2017/745, to certify that the products of our company fulfilled the requirements of the Appendix I of MDR (EU) 2017/745.

The clinical evaluation will focus on performance evaluation, bench testing and pre-clinical evaluation, the Medical isolation gown, must give a evidence of the clinical performance and safety is qualified, appropriate and adequate to conform with the pertinent General Safety and Performance Requirements of the Regulation, and risks and side effects is acceptable when weighed against the intended benefits of the device.

Risks and side effects is acceptable when weighed against the intended benefits of the device. And according to the CER conclusion, the company shall conduct PMS for the product, and, no clinical investigation, no PMCF needed.

2. Justification on Route of this clinical evaluation

2.1 Brief information on the device

The medical device is intended to be worn by healthcare providers or visitors to isolate themselves from patients, helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it may help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Single-use, Non-sterile.

Contraindications:

Users who is allergic to PP+PE, PP, SMS, PE materials.

Specifications: PP+PE, PP, SMS, PE

Validity of Medical isolation gown: 3 years.

GMDN code: 35492

UMDN code: 15037

Design principle of the device:

The Medical isolation gown is designed and manufactured according to EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018 and other relative standards, all types and specifications of Medical isolation gown manufactured by our company are in line with the standard.

2.2 Justification on Route of clinical evaluation based on Article 61 (10) of MDR (EU) 2017/745

According to Article 61 (10) of MDR (EU) 2017/745:

“Without prejudice to paragraph 4, where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre- clinical evaluation, to be adequate. ”

And also, reference to MDCG 2019-15 Guidance notes for manufacturers of class I medical devices Dec.2019:

“In duly justified and substantiated cases, some Class I devices manufacturers may exceptionally demonstrate that the conformity with general safety and performance requirements based on clinical data is not deemed appropriate. Such a justification by the manufacturer must be based upon an evaluation of evidence in accordance with Article 61(10).”

2.2.1 Device technology and critical clinical use risks

The Medical isolation gown is a disposable device intended for medical purposes that is worn on the examiner’s hand or finger(s) to prevent contamination between patient and examiner.

In the industry, because there are specific and detailed product standards for the Medical isolation gown, including definition of product specification, structures, shapes, and technical parameters, test method, almost all manufacturer produce the Medical isolation gown based on the applied standards: EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018.

The device main performance parameters focus on the material physical performance. Therefore, the risks of Medical isolation gown lies in two part:

1) Product physical performance;

2) Production process control during manufacturing;
3) Use method, such as not for repeated use.

According to risk management and post-market information, following are identified clinical risks related to use of the Medical isolation gown:

	Risks description
Review of pre-clinical study	H1. Bacterial infection: due to halfway sterilize or damaged packaging H2.Unqualified Bio-compatibility cause allergic reaction, toxicosis: material or packaging material is not medical class H3. Baneful chemical matter included: material or packaging material is not medical class H4. Use the Medical isolation gown on other conditions which is not its indications. H5.Packing bags are damaged H6. Contamination or deterioration. H7. Products that are beyond expiry date may be used. H8. Repeated use: incorrect use or improper guidance led by inadequate or error of labeling or attention items H9. Wrong specification H10. Unqualified process control on process of materials mixing, defoaming, dipping, drying. H11. Bad performance such as Resistance to microbial penetration, Cleanliness, Linting, Bursting strength, Tensile strength. H12. Unreasonable disposal. H13. Production lot number can not be traced. H14. Mixture of different specifications. H15. Unqualified materials such as PP+PE, PP, SMS, PE, . H16. Stains in the Medical isolation gown. H17. Inadequate information provided to users. H18. Breakage of Medical isolation gown H19. Shipping problem
Feedback or adverse events of equivalence device	None
Feedback or adverse events of same category device	1) Hair inside cause pollution of product 2) Allergic reaction to users

2.2.2 Therapeutic alternatives method

There are other alternative methods such as other type Medical isolation gown or protective device, compared with them, the examination Medical isolation gown is

easy to use, low cost, also effective.

2.2.3 Standards and bench testing

As described in section 2.2.1, the Medical isolation gown is produced based on following standards for its specification, technical parameters, and test method.

EN 13795-2:2019	Surgical clothing and drapes - Requirements and test methods -Part 2 Clean air suits
ISO 9073-10:2003	Surgical drapes, gowns and clean air suits for patients, clinical staff and equipment - Part 4: Test method for linting in the dry state
EN ISO 22612:2005	Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration
ISO 22610:2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration

2.2.4 Justification conclusion

Through analysis from section 2.2.1 to 2.2.3, we knows that:

1) The Medical isolation gown is very mature device with mature technology state;
2) The Medical isolation gown main risks lies in material control, manufacturing control and use; these risks can be identified adequately during design stage and post market surveillance;
3) In the industry, the Medical isolation gown is on standard production based on clear definition on products' specification, shapes, technical parameters, and test method based on EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018;
4) There are other alternatives method for the same indication, but the Medical isolation gown is easy to use, low cost, also effective.

In summary, General Safety and Performance Requirements on the Medical isolation gown can be evaluated based on risk management, bench testing, performance evaluation, no clinical data is deemed.

Therefore, we conclude that the Medical isolation gown can be evaluated based on Article 61 (10) of MDR (EU) 2017/745.

3. Basic information of the device

3.1 Product specifications

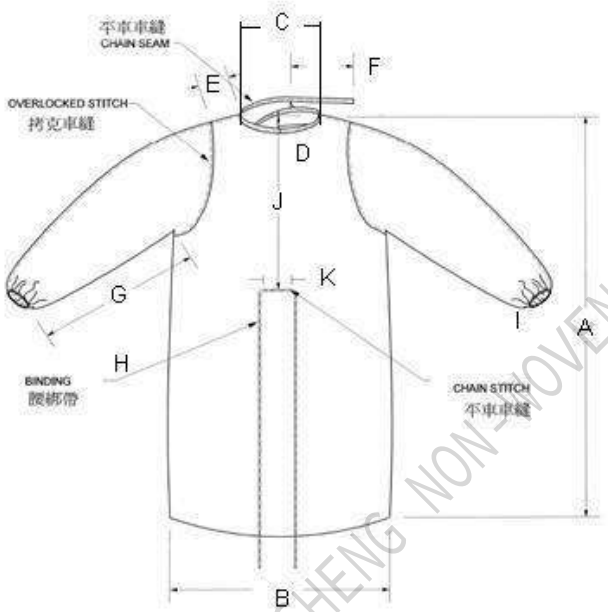
The Medical isolation gown have two material types : PP+PE, PP, SMS, PE.

Material	PP+PE, PP, SMS, PE		
Model	S	M	L

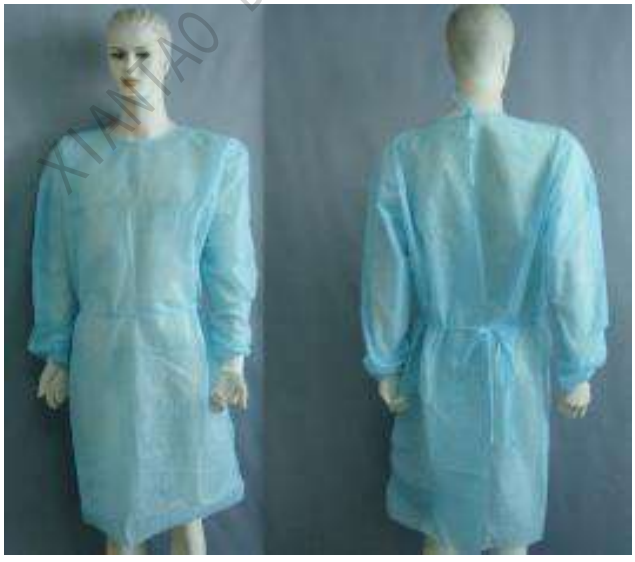
L x W（cm)	110x130	115x137	120x140
Sleeves (cm)	56	56	56
Cuff (cm)	16	16	16
Deviation (cm)	± 1.5	± 1.5	± 1.5

3.2 Product structure

The structure of Medical isolation gown as follows:



3.3 Product pictures



3.4 Product performance

Item	Technical parameters
Appearance	The Medical isolation gown shall be clean, no foreign matters, no stain.
Dimensions	It shall comply the specification requirements.
Resistance to microbial penetration - Dry	≤ 2 Log_{10} (CFU)
Cleanliness - Mircrobial	≤ 2 Log_{10} (CFU/dm^2)
Cleanliness - Particulate matter	≤ 3,5 IPM
Linting	≤ 4,0 Log_{10} (lint count)
Bursting strength - Dry	≥ 40kPa
Tensile strength - Dry	≥ 20N
Moisture permeability (g/(m^2.24h)	≥ 2500
Impermeability (kPa)	≥1.67
Breaking force (N) Longitudinal direction Transverse direction	 ≥45 ≥45
Elongation at break Longitudinal direction Transverse direction	 ≥15 ≥15
Water staining (class)	≥3
Vertical combustion 7) After-flame time(s) Longitudinal direction Transverse direction 8) Continuous flame times (s) Longitudinal direction Transverse direction 9) Damaged length (mm) Longitudinal direction Transverse direction	 ≤10 ≤10 ≤15 ≤15 ≤200 ≤200

3.5 Package of device

The Medical isolation gown has two packages, internal package and external package.

Internal package	PE bag, 10 pcs/bag
External package	Corrugated box, 100 pcs/carton

4. Performance evaluation and bench testing

The company conduct adequate pre-clinical study for the Medical isolation gown,

according to Preclinical Assessment (section 8 of the CE technical documentation, XTDC/CE03-01, A/0), the company implemented Physical performance test, shelf life study and bio-compatibility test for the dental based on applies standards.
There test information summarized as follows:

Test item	Applied standards	Criteria/ Result
Product performance test	Company standard*	Qualified
Bio-compatibility requirement test	ISO 10993-10: 2010	Qualified
Product transport validation report	ASTM D 4169-16	Qualified
Self-Life report	Company standard*	Qualified

*Company standard: the company standards includes all requirements related to EN 13795-2:2019, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018.

According to test results, the dental complies with applied standards and its claim performance requirements.

5. Requirement on acceptable benefit/risk profile

5.1 Evaluation of the device's benefits to the patient

Reference to section 3 of Benefit-Risk analysis report XTDC/CE03-01-07 (XTDC/CE03-01-05, A/0).
According to the evaluation on benefit of the device, the benefit is in the high level.

5.2 Evaluation of the clinical risks of devices

5.2.1 Clinical risks identified
See section 2.2.1, following risks identified:
H1. Bacterial infection: due to halfway sterilize or damaged packaging
H2.Unqualified Bio-compatibility cause allergic reaction, toxicosis: material or packaging material is not medical class
H3. Baneful chemical matter included: material or packaging material is not medical class
H4. Use the Medical isolation gown on other conditions which is not its indications.
H5.Packing bags are damaged
H6. Contamination or deterioration.
H7. Products that are beyond expiry date may be used.
H8. Repeated use: incorrect use or improper guidance led by inadequate or error of labeling or attention items
H9. Wrong specification
H10. Unqualified process control on process of materials mixing, defoaming, dipping, drying.
H11. Bad performance such as Resistance to microbial penetration, Cleanliness, Linting, Bursting strength, Tensile strength.

H12. Unreasonable disposal.
H13. Production lot number can not be traced.
H14. Mixture of different specifications.
H15. Unqualified materials such as PP+PE, PP, SMS, PE, .
H16. Stains in the Medical isolation gown.
H17. Inadequate information provided to users.
H18. Breakage of Medical isolation gown
H19. Shipping problem
H20 Hair inside cause pollution of product
H21 Allergic reaction to users

5.2.2 Assessment of clinical risks
Step 1: Adopts the same risk management matrix from the Risk management document, see Risk management report ;

Step 2: Risk assessment of identified clinical risks
These 21 risks are fully identified and controlled by risk control measures. According to assessment in Risk management report (XTDC/CE03-01-07, A/0), through control measures taken, the clinical risks are controlled to acceptable level.

5.3 Evaluation of acceptability of the benefit/risk profile
The non-sterile non-woven examination Medical isolation gown is a disposable device intended for medical purposes that is worn on the examiner's hand or finger(s) to prevent contamination between patient and examiner. Its benefits for users is in the high level.

Considering that the risk control measures are clear and acceptable.According to a quantitative benefit evaluation in section 3, the benefits of the product are acceptable; according to risk evaluation in section 4 and Risk analysis report XTDC/CE03-01-07 , all identified risks are controlled to an acceptable level.

According to the evaluation of the device's intended purpose, the device's benefits to the patient and clinical risks of devices during usage, consider nature, extent/severity, probability/frequency, duration of benefits to the patients and of undesirable side-effects and other risks. It can conclude that the benefits patients gained from this product are widely higher than its risks.

6. Conclusion
6.1 Summary
It can be concluded from above narration that the products with CE marking of this company, Medical isolation gown, can be safe, little risks and in accordance with General Safety and Performance Requirements of MDR (EU) 2017/745.

The benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives, is acceptable.
The information materials supplied by the CE technical documents is adequate.
The device, including its IFU, for the intended users, usability aspects and discrepancies, is suitable.
Between these documents and the current knowledge/ the state of the art, discrepancies, is consistent.
Residual risks and uncertainties or unanswered questions will be traced by PMS, also due to residual risks analysis, the risks related to the product caused by the purchasing materials, manufacture process, and technical design which are very mature and common, can be traced by PMS enough, no need to conduct PMCF and clinical investigation needed.
Above all, the device is acceptable for CE-marking.

6.2 Conclusion of clinical investigation implementation

Based on the evaluation on product on performance evaluation, bench testing and pre-clinical evaluation, risk management output. Conclusion can be made that product hazards can be evaluated adequately by the clinical equivalence, clinical literature, no clinical investigation is needed. Residual risks and uncertainties or unanswered questions will be traced by PMS.

6.3 Conclusion of implementation of Post market clinical follow-up (PMCF) studies

Once pre-market data of product is of limitation and insufficient for proving the product meeting General Safety and Performance Requirements of MDR (EU) 2017/745, post market clinical follow-up (PMCF) studies is an option to monitor post market data of product. According to MEDDEV 2.12/2 rev2, the decision to conduct PMCF studies must be based on the identification of possible residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk ratio.

In order to justify if PMCF is need, following circumstances are considered.

Circumstances	Analysis	Conclusion
-innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel;	Mature technology, no innovation of operation principle for the device.	N.A
-significant changes to the products or to its intended use for which pre-market clinical evaluation and re-certification has been completed;	No any change,	N.A
-high product related risk e.g. based on design, materials, components, invasiveness, clinical	Considering intended use, work function, the device is	N.A

procedures	low risk	
-high risk anatomical locations;	Does not involve anatomical location	N.A
-high risk target populations e.g. paediatrics, elderly;	Not for paediatrics use	N.A
-severity of disease/treatment challenges;	It is not the scope of intended use of the device	N.A
-questions of ability to generalise clinical investigation results;	No clinical investigation needed based on section 6.2 conclusion	N.A
-unanswered questions of long-term safety and performance;	No unanswered questions of long-term safety and performance	N.A
-results from any previous clinical investigation, including adverse events or from post-market surveillance activities;	No the result	N.A
-identification of previously unstudied subpopulations which may show different benefit/risk-ratio e.g. hip implants in different ethnic populations;	No unstudied subpopulations	N.A
-continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product;	The product shelf time is validated	N.A
-risks identified from the literature or other data sources for similar marketed devices;	Risks identified, and after risk control measures taken, compared to clinical benefit, these clinical risks are acceptable.	N.A
-interaction with other medical products or treatments;	Not applicable	N.A
-verification of safety and performance of device when exposed to a larger and more varied population of clinical users;	The user population is clearly defined and no larger and more varied population.	N.A
-emergence of new information on safety or performance;	No new information on safety or performance	N.A
-where CE marking was based on equivalence.	No	N.A

In summary, there is only one circumstance applied to the device, and the match use study was implemented and qualified.

Conclusion can be made that product General Safety and Performance Requirements can be evaluated adequately, the medium/long-term safety and clinical performance are already known from previous use of the device, no clinical post market clinical

follow-up (PMCF) study is needed.

7. Date of the next clinical evaluation

7.1 Time of updates

The company will define the updating time yearly according to related information achieved in production process, clinical literature and PMS results. When defining the updating time, following information shall be considered:

	Considered information	Present evaluation
Q1	Whether the device carries significant risks, including design, materials, components, clinical procedures etc. which may exist at present or will be found in future.	At present, according to risk management analysis, and clinical evaluation above mentioned, the device does not carry significant risks.
Q2	Whether the device is well established, shall consider: -innovation; -relevant changes in clinical sciences, materials sciences or other sciences related to the device; -current level of device clinical performance and clinical safety.	-the device adopts mature technologies; -there is no these changes; -according to clinical feedback, the device is safe both of performance and clinical safety. Therefore, the device is well established.
Q3	Whether there are risks and uncertainties or unanswered questions.	No
Q4	Design changes or changes to manufacturing procedures.	No

7.2 General considerations when updating the CER

PMS shall be considered when updating the CER, and will be inputted as an important information.

When updating the CER, following shall be verified:

a) if the benefit/risk profile, undesirable side-effects (whether previously known or newly emerged) and risk mitigation measures are still

-compatible with a high level of protection of health and safety and acceptable according to current knowledge/ the state of the art;

- correctly addressed in the information materials supplied by the manufacturer of the device;

- correctly addressed by the manufacturer's current PMS plan;

b) if existing claims are still justified;

c) if new claims intends to use are justified.

According to above evaluation, the company will update the CER every year.