CE Technical Files

Shoe Cover

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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	---	Zhang Yueqiong	2021.02.25

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Technical File

<Product: Shoe Cover>
<Document No.: CE/MDR-HBZC-03-01>
<Date of issue: 2021.02.25>

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Hubei Zhencheng Nonwoven Products Co., Ltd.
Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

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1 General Description

1.1 Device description and specification

Shoe Cover is used in hospital, clinic, beauty salon, purification workshop or clean room to keep from external harmful material.

This device is a disposable product, suitable for the health care of the wearer in the general medical environment and the general care in public health places to prevent unwanted dust, liquid and other substance.

Shoe Cover is going to contact with the intact skin of the user, and it has been tested according to related compatibility standards including ISO 10993-1:2018, EN ISO10993-5： 2009 and EN ISO 10993-10:2013, please refer to Annex 3< biocompatibility test report>.

The product images and specification of Shoe Cover are shown as below.

The Shoe Cover product image is shown as below.

Figure1 Product picture

Intended Use
The product provides general protection. It can be used as general isolation in clinic, ward or laboratory. It is not intended to use in operation room.

Model
Non woven shoe cover, PE/CPE shoe cover

Size
S, M, L, XL

Packaging
The products were generally packed 100 pcs per polybag, and 2000 pcs per carton. Also we can pack the quantity and pack system style under the customer's requirements.

Material: pp nonwoven + Environmental elastic or PE/CPE + Environmental elastic

Storage

The product should be stored in a cool, dry, well ventlated and clean environment. Keep away from direct sunlight and heat source.

How to use the device

Wear on feet or shoes directly.

Shelf Life

2 years

Caution

1.This product is for one-time use only.
2.It shall be properly treated as required and followed the local laws and regulations after use.
3.Never share your product with others.
4.Wash your hands thoroughly upon removal of the product.
5.Use with caution when you are allergic to nonwoven fabrics.

Warning

1. Once the Shoe Cover get dirty and cannot provide further protection, please change another new one.
2. Only for single use.

Disposal

Please dispose the product after use to comply with local regulation.

Harmonized standards

No.	Standard No.	Version	Title
1	(EU) 2017/745	2017	Medical Device Regulation
2	EN ISO 14971	2019	Medical Device -Application of Risk Management to Medical Device
3	EN ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
4	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management

			process
5	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
6	EN ISO 10993-10	2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
7	EN 1041	2008+A 1:2013	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices

Classification

According to Rule1, Annex VIII (Rule1: All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies) of Regulation (EU) 2017/745, based on the intended use of Shoe Cover, it shall be Class I.

UDI

We will apply the UDI and have the UDI-DI placed on the label of devices before May 26, 2025 as per the requirement of Article 123, 3f) of Regulation (EU) 2017/745.

SRN

We plan to get SRN by registering in EUDAMED once it's fully functional as soon as the product is evaluated to conform to Regulation (EU) 2017/745.

1.2 Reference to previous and similar generations of the device

This product is made of non-woven fabric.

Shoe Cover is very commonly used product in hospital, there are many similar shoes cover used in hospital.

We develop the Shoe Cover based on the similar product which has been sold and widely use in the market, no previous and similar generations of the device was exist.

2 Information to be supplied by the manufacturer

2.1 Label and Language

2.1.1 General

This Clause contains symbols that are already in use, and are deemed to be suitable without need for further explanation.

NOTE Symbols used with medical devices for use by other than healthcare

professionals can require additional explanations.

2.1.2 Symbol for "DO NOT REUSE"

NOTE 1 Synonyms for "Do not reuse" are "single use, "Use only once"

2.1.3 Symbol for “BATCH CODE”

This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.

NOTE 1 The relative size of the symbol and the size of the batch code are not specified.

NOTE 2 Synonyms for "batch code" are "lot number", "batch number".

2.1.4 Symbol for "DATE OF MANUFACTURE"

This symbol shall be accompanied by a date to indicate the date of manufacture, expressed as given in ISO 8601, as four digits for the year, and where appropriate, two digits for the month and two digits for the day. The date could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol.

NOTE 1 The relative sizes of the symbol and the date are not specified.

2.1.5 Symbol for "CATALOGUE NUMBER"

The manufacturer's catalogue number shall be after or below the symbol adjacent to it.

NOTE 1 The relative size of the symbol and the size of the catalogue number are not specified.

NOTE 2 Synonyms for "catalogue number" are "reference number", "re-order number".

2.1.6 Symbol for "CAUTION"

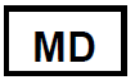
NOTE 1 This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol “Caution” is still sometimes used to have the meaning of “Attention, see instructions for use”.

2.1.7 Symbol for "MANUFACTURER"

This symbol shall be accompanied by the name and the address of the manufacturer (the person placing the device on the market), adjacent to the symbol.

2.1.8 Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

2.1.9 Symbol of “Medical Device”



2.1.10 Symbol of “NON-STERILE”

2.1.11 Symbol of “Do not use if package is damaged”

2.1.12 Symbol of “Consult instructions for use”

2.1.13 Symbol of “Use-by date”

NOTE The relative size of the symbol and the size of the name and address are not specified.

b) Diameter of the pattern shall not be less than 5mm.

c) CE marking shall be distinct, visible, durable and in clear writing.

After passing CE certification, mark of CE needs to be printed on labels;

a) Pattern CE

b) Diameter of the pattern shall not be less than 5mm.

c) CE marking shall be distinct, visible durable and in clear writing.

Language Requirements for Labeling in the EU Member States

Language / Country	Danish	Dutch	English	Finnish	French	German	Greek	Icelandic	Italian	Norwegian	Portuguese	Spanish	Swedish	Czech	Estonia	Russian	Hungarian	Latvian	Lithuanian	Polish	Slovak	Slovenia
Austria						★																
Belgium		★			★	★																
Denmark	★																					
Finland				★									★									
France					★																	
Germany						★																
Greece							★															
Holland		★																				
Iceland								★														
Ireland			★																			
Italy									★													
Luxembourg					★	★																
Norway										★												
Portugal											★											
Spain												★										
Sweden													★									
Swiss					★	★																
UK			★																			
Cyprus							★															
Czech														★								
Estonia			★												★	★						
Latvia			★													★		★				

Lithuanian																			★			
Malta			★																			
Poland																				★		
Slovakia																					★	
Slovenia																						★
Hungary																★						

2.2 label

Please refer to <labeling> (CE/MDR-HBZC-03-07)

2.3 Instruction for use

Please refer to <Instruction for Use> (CE/MDR-HBZC-03-08)

3 Design and Manufacturing Information

Introduction of Manufacture

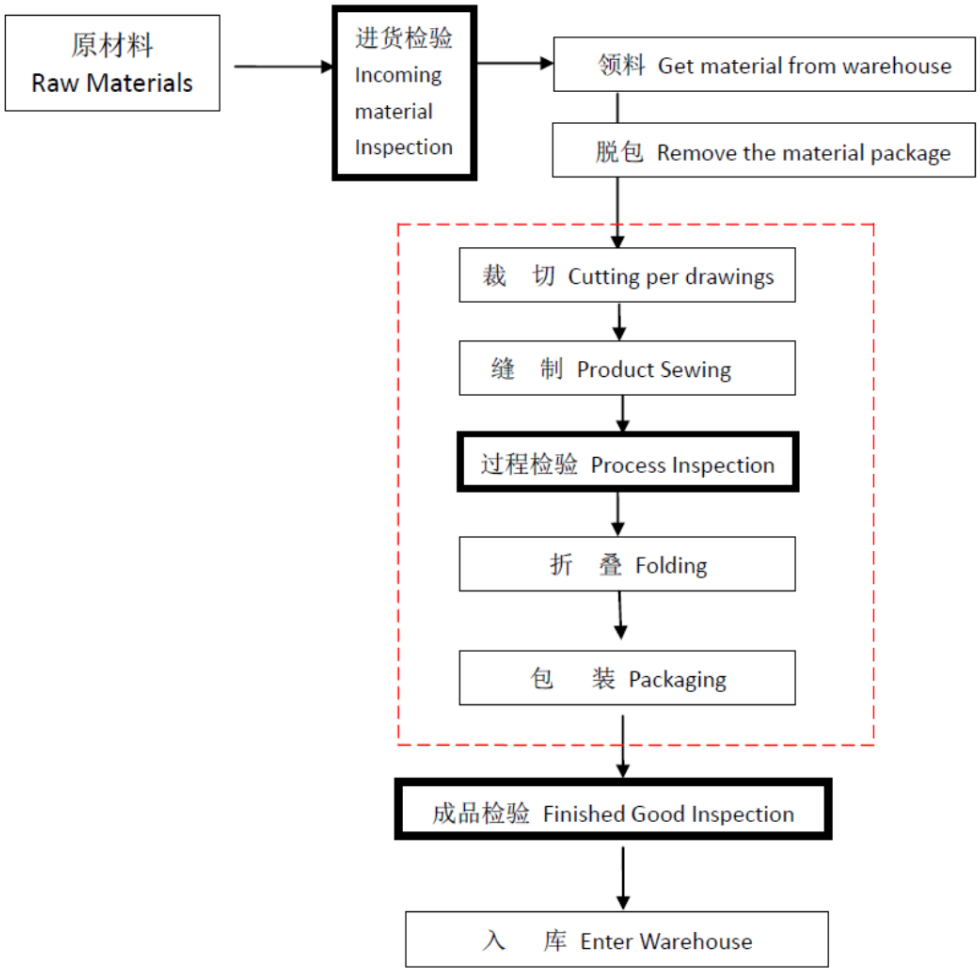
Name: Hubei Zhencheng Nonwoven Products Co., Ltd.

Address: Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

Hubei Zhencheng Nonwoven Products Co., Ltd Specializes in Nonwoven & Plastic products include disposable nonwoven cap, face mask, nonwoven shoe cover and plastic shoe cover etc. Factory located in Xiantao city, which is close to Wuhan abt only 1 h. Superior geographical enviroment and conveient transportation and powerful logistics system

Manufacturing Information

The manufacturing flowchart is shown as below.



注：Note

1. 为检验点 Inspection points
2. 生产控制区 Production control points

Figure2 Manufacturing process

Quality Control

We Hubei Zhencheng Nonwoven Products Co., Ltd. control our product quality based on our quality management system. We control the product quality from following aspects: 1) In coming inspection, 2) Manufacture process, 3) Process and final product inspection.

1)We choose our qualified supplier according to HBZC-QP-10 < Purchase Control Procedure >, after choosing the qualified supplier, the supplier will offer the qualification or inspection report of the raw material. When the raw material arrives at

the factory, in coming inspection will conduct to ensure the raw material meet the requirements. The qualified suppliers are shown in the table below

2) Manufacturing process will be validated to ensure the manufacture process will produce qualified product, non-conformity will be strictly control by HBZC-QP-17<Non-conformity Product Control Procedure>.

3) Process inspection will be performed during the manufacturing process to avoid the unqualified products. Final inspection will be performed to ensure only qualified products will be deliver to the customer.

4 General Safety and Performance Requirements

Please refer to file CE/MDR-HBZC-03-03 <General Safety and Performance Requirements >

5 Benefit-Risk Analysis and Risk Management

Please refer to file CE/MDR-HBZC-03-04 <Risk Management Report>

6 Product Verification and Validation

- The material used to manufacture Shoe Cover has passed the Biocompatibility test, the test reports are attached as Annex 3 <Biocompatibility Test Report>.

6.1 Pre-Clinical and clinical data

Please refer to file CE/MDR-HBZC-03- 05 <Clinical Evaluation Report>

6.2 Additional information required in specific cases

Shoe Cover is wildly used in the hospital, clean room and other environment which need protection. No additional information in specific cases is required.

7 Post Marketing

7.1 Post-market Surveillance Plan

This Post-Market Surveillance Plan (PMS) plan is to address the residual risks identified related to clinical safety and clinical performance of the device.

PMS methodologies

a) The PMS methodologies are carried out through reviewing relevant retrospective

data from patients previous exposed to Shoe Cover. Quality and Customer Service gather the customer feedbacks, and reviewing on a monthly basis.

b)Post-market clinical surveillance studies are performed on the devices within their intended use according to the instructions for use.

c) Device intended use:

The product provides general protection. It can be used as general isolation in clinic, ward or laboratory. It is not intended to use in operation room.

d)The clinical investigation plan /study plan:

1)Study population and group of patients shall include the following population. The study population is selected based on the product intended use.

2)Quality department and customer service are responsible for analyzing the customer feedback and submit management team to review.

3)Study objectives are to gather customer feedbacks for 1,000 units or one year patients follow-up for each type of production. After analysis, Sales and quality team will determine the endpoint of the study.

4)PMS studies shall be conducted by product type.

5) Where appropriate, such as a new risk identified through the PMS, the interim report need to be generated to ensure continuous risk management based on clinical data.

6) In case of natural disaster, it might terminate the early study in the PMS site.

7) After gathering the clinical data, follow the following procedure to control data and update the risk analysis when appropriate.

Table 1: PMS Study population selection, methodologies and timing design

PMS Method	Department	Time and frequency
1 Investigate people who are seriously ill	Sale Department	When serious illness occurs to persons using the product
2 Visit long - term service personnel	Sale Department	When there are people who use the product for a long time
3 Survey sensitive people	Sale Department	When a sensitive person uses the product
4 Continue to study the relevant literature	Production Department	The relevant clinical literature should be updated once a year
5 Continuing research on similar medical devices aftermarket release	Production Department	Long-term continuous study
6 Continuing research on the	Production	Long-term continuous study

materials, operating principles and techniques of medical devices	Department	
7 Continuous research into new technologies	Production Department	When there were new technology
8 Continuous research on product life	Quality Department	Long-term continuous study
9 Study adverse events and establish and implement the medical device notification and withdrawal control procedures	Quality Department	When adverse event occurs
10 Solicit relevant improvement opinions from customers, measure customer satisfaction, and establish and implement customer related process control procedures	Sale Department	Once a year
11 Solicit relevant improvement opinions from customers, measure customer satisfaction, establish and implement customer satisfaction survey control procedure	Sale Department	When there was customer complain happened
12 Pay close attention to the recalled products and establish and implement the medical device notification and withdrawal control procedures.	Sale Department	When there were product recall
13 Research on new product related standards	Production Department	When product related standards are updated

14 Study of new product-related regulations	Production Department	When product related standards are updated

Risk Analysis of Post marketing Surveillance
Risk analysis indicates all risks associated with the identified hazards have been evaluated. After appropriate retirement actions of reducing these risks have been taken, the overall level of risks of the product is acceptable with regard to the intended application and use of the products. Therefore, the post-marketing follow-up plan is designed to follow up the clinical performance of the device through Shoe Cover customers and analysis.

7.2 Post-market Surveillance Report

7.2.1 Post-market Surveillance data

Base on the post-market surveillance plan we made in section 7.1, the corresponding data collected are shown as follow.

The Shoe Cover has been placed on the market for many years. We did not receive customer complains about product effectiveness and safety. The customer feedback of the propose device and similar device are shown in the table below.

Table2 Customer feedback list of the propose device

NO.	Description	Root Cause	Corrective actions	state
0	/	/	/	/

Table3 Post Market experience of similar device

Area	Time	Quantity	Complaints	Adverse events
China	2018	600,000,000.00	0	0
	2019	700,000,000.00	0	0
	2020	1,000,000,000.00	0	0
EU	2018	10,000,000.00	0	0
	2019	20,000,000.00	0	0
	2020	50,000,000.00	0	0
USA	2018	200,000,000.00	0	0
	2019	400,000,000.00	0	0
	2020	600,000,000.00	0	0
Total	3,580,000,000.00			

Table4: PMS Study Result

PMS Method	Department	Collecting Data
1 Investigate people who are seriously ill	Sale Department	None, this product is not intended for persons with serious illness
2 Has an interview on long term use people	Sale Department	None, this product has no long-term use of personnel
3 Survey sensitive people	Sale Department	None, no sensitive person USES this product
4 Continue to study the relevant literature	Production Department	Refer to file CE/MDR-HBZC-03-05 Clinical Evaluation Report
5 Continuing research on similar medical devices aftermarket release	Production Department	Refer to file CE/MDR-HBZC-03-05 Clinical Evaluation Report
6 Continuing research on the materials, operating principles and techniques of medical devices	Production Department	The material, operating principle and technology of this product are not updated
7 Continuous research into new technologies	Production Department	No new technology
8 Continuous research on product life	Quality Department	No change in life period
9 Study adverse events and establish and implement the medical device notification and withdrawal control procedures	Quality Department	None, no adverse event

10 Solicit relevant improvement opinions from customers, measure customer satisfaction, and establish and implement customer related process control procedures	Sale Department	None, no customer feedback.
11 Solicit relevant improvement opinions from customers, measure customer satisfaction, establish and implement customer satisfaction survey control procedure	Sale Department	None, no customer complains
12 Pay close attention to the recalled products and establish and implement the medical device notification and withdrawal control procedures.	Sale Department	None, no product recall
13 Research on new product related standards	Production Department	None
14 Study of new product-related regulations	Production Department	The Europe Regulation about medical device (EU) 2017/745 has been released on 20th, May, 2017. We update this CE document based on the new Medical Device Regulation (2017/745). And implement quality management base on the new Medical Device Regulation (EU) 2017/745.

7.2.2 Safety and Effectiveness Conclusion

By collecting and analyzing PMS data of the propose device and similar device, the

technology of Shoe Cover is mature. Risk management, bench test, literature analysis and post- market data has proven the safety and effectiveness of the propose device. The risk identified in the device risk management documentation and literature has been controlled. All the hazards and other clinically relevant information have been identified appropriately. The literature results are enough to address the points we aim to clarify and there is no need to get the new clinical information.

From the PMS data of the similar device, there is no significant risk were identified and at the same time, the intended use was proved to be effective. The benefit is higher than the risk.

8 Declaration of Conformity

Please refer to file CE/MDR-HBZC-03-02 < Declaration of conformity >.

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-HBZC-03.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Hubei Zhencheng Nonwoven Products Co., Ltd.

Address: Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

Product Information

Name: Shoe Cover

Model: Non woven shoe cover, PE/CPE shoe cover

GMDN: 15056

Basic UDI-DI: /

Classification: Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: 董彩秋 Date: 2021年3月1日

Position: General Manager Place: Hubei / China

General Safety and Performance Requirements

File No.: CE/MDR-HBZC-03-03

Version: A/0

Product: Shoe Cover

Issued By	Reviewed By	Approved By	Effective Date
Zhang Yueqiong	Tang Meirong	Ceng Xinquan	2021.02.25

Hubei Zhencheng Nonwoven Products Co., Ltd.
Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Zhang Yueqiong	2021.02.25

4 General Safety and Performance Requirements

Item	The requirement of Medical Device Regulation 2017/745	Applicable	Standard	Evidence of Conformity
GENERAL REQUIREMENTS				
1	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.	A	ENISO15223-1：2016 ENISO14971：2019 ISO10993-1：2018 ENISO10993-5：2009 ENISO10993-10：2013	Label & IFU CE/MDR-HBZC-03-07&CE/MDR-HBZC-03-08 Risk Management Report CE/MDR-HBZC-03-04 Biocompatibility Test Report refer to Annex3 <Biocompatibility Test Report>
2	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.	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04
3	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 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	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04

	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.			
4	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.	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04
5	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,	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04

	professional, disabled or other users).			
6	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.	A	ENISO15223-1：2016 ENISO14971：2019 ISO10993-1：2018 ENISO10993-5：2009 ENISO10993-10：2013	Label & IFU CE/MDR-HBZC-03-07&CE/MDR-HBZC-03-08 Risk Management Report CE/MDR-HBZC-03-04 Biocompatibility Test Report refer to Annex3 <Biocompatibility Test Report>
7	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.	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04
8	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.	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04
9	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.	NA		

REQUIREMENTS REGARDING DESIGN AND MANUFACTURE				
10	Chemical, physical and biological properties			
	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: (a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability; (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; (c) the compatibility between the different parts of a device which consists of more than one implantable part; (d) the impact of processes on material properties; (e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; (g) surface properties; and (h) the confirmation that the device meets any defined chemical and/or physical specifications.	A	ENISO15223-1：2016 ENISO14971：2019 ISO10993-1：2018 ENISO10993-5：2009 ENISO10993-10：2013	Label & IFU CE/MDR-HBZC-03-07&CE/MDR-HBZC-03-08 Risk Management Report CE/MDR-HBZC-03-04 Biocompatibility Test Report refer to Annex3 <Biocompatibility Test Report>
	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.	A	ENISO15223-1:2016 EN1041:2008+A1 2013	Label & IFU CE/MDR-HBZC-03-07&CE/MDR-HBZC-03-08
	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	NA		

	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 use.			
	10.4. Substances			
	10.4.1. Design and manufacture of devices 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: — are invasive and come into direct contact with the human body, — (re)administer medicines, body liquids or other substances, including gases, to/from the body, or — transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, 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: (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 (1), or (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	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04

	Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.			
	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 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.	NA		
	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 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,	NA		

	the guidelines shall be updated.			
	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.	NA		
	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.	A	ENISO15223-1:2016 EN1041:2008+A1 2013	Label & IFU CE/MDR-HBZC-03-07&CE/ MDR-HBZC-03-08
	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.	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04
	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.	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04
11	11. Infection and microbial contamination			
	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,	A	ENISO14971：2019	Risk Management Report CE/MDR-HBZC-03-04

	other persons. The design shall: (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.			
	11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	A	ENISO15223-1:2016 EN1041:2008+A1 2013	Label & IFU CE/MDR-HBZC-03-07&CE/ MDR-HBZC-03-08
	11.3. Devices labelled as having a specific microbial state shall 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.	NA		
	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.	NA		
	11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	NA		
	11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	NA		
	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	NA		

	sterilisation indicated by the manufacturer.			
	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.	NA		
12	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.	NA		
	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.	NA		
	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.	NA		
	13. Devices incorporating materials of biological origin	NA		
	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;	NA		

	(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.			
	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, 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	NA		
	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	NA		

	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 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.			
14	14. Construction of devices and interaction with their environment	NA		
	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.	NA		
	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; (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; (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; (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; (e) the risks of accidental ingress of substances into the device;	NA		

	(f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and (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.			
	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.	NA		
	14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	NA		
	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.	NA		
	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.	NA		
	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 their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.	NA		
15	15. Devices with a diagnostic or measuring function	NA		
	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.	NA		

	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	NA		
16	16. Protection against radiation	NA		
	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. (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.	NA		
	16.2. Intended radiation (a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing 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. (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.	NA		
	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	NA		

	exposure to radiation of patients, users and other persons who may be affected.			
	16.4. Ionising radiation (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. (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. (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.	NA		
17	17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves	NA		
	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.	NA		
	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.	NA		

	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).	NA		
	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.	NA		
18	18. Active devices and devices connected to them	NA		
	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.	NA		
	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.	NA		
	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.	NA		
	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.	NA		
	18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.	NA		
	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.	NA		
	18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible,	NA		

	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.			
	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.	NA		
19	19. Particular requirements for active implantable devices	NA		
	19.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as 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 highfrequency 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.	NA		
	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 substances they are intended to administer, and — the reliability of the source of energy.	NA		
	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.	NA		
	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	NA		

	manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.			
20	20. Protection against mechanical and thermal risks	NA		
	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.	NA		
	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.	NA		
	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.	NA		
	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.	NA		
	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.	NA		
	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.	NA		
21	21. Protection against the risks posed to the patient or user by devices supplying energy or	NA		

	substances			
	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.	NA		
	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.	NA		
	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.	NA		
22	22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	NA		
	22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform 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.	NA		
	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	NA		

	— 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.			
	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.	NA		
	REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE			
23	23. Label and instructions for use	A	ENISO15223-1:2016 EN1041:2008+A1 2013	label & IFU CE/MDR-HBZC-03-07&CE/ MDR-HBZC-03-08
	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: (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. (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.	A	ENISO15223-1:2016 EN1041:2008+A1 2013	label & IFU CE/MDR-HBZC-03-07&CE/ MDR-HBZC-03-08 Printed label and IFU was used.

	(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. (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. (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. (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. (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. (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.			
	23.2. Information on the label The label shall bear all of the following particulars: (a) the name or trade name of the device; (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; (c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	A	ENISO15223-1:2016 EN1041:2008+A1 2013	Label & IFU: CE/MDR-HBZC-03-07&CE/ MDR-HBZC-03-08 a) The device name is indicated. b) See [Intended Use]

	(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; (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; (f) where applicable, information labelled in accordance with Section 10.4.5.; (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; (h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII; (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; (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; (k) an indication of any special storage and/or handling condition that applies; (l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method; (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 use, taking into account the intended users; (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; (o) if the device is a single-use device that has been reprocessed, an indication of that fact, the			c) Hubei Zhencheng Nonwoven Products Co., Ltd. Address: Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China d) European Authorized Representative info.: SUNGO Europe B.V. Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands e) N/A f) N/A g) LOT NUMBER h) UDI-DI will be applied. i) The Shelf Life is 2 years.

	number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles; (p) if the device is custom-made, the words ‘custom-made 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’; (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; (s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.			j) Manufacture date was indicated on label. k) Storage condition was indicated in IFU. l) N/A m) N/A n) N/A o) N/A p) N/A q) N/A r) N/A s) N/A
	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: (a) an indication permitting the sterile packaging to be recognised as such, (b) a declaration that the device is in a sterile condition, (c) the method of sterilisation,	NA		

	(d) the name and address of the manufacturer, (e) a description of the device, (f) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’, (g) if the device is custom-made, the words ‘custom-made device’, (h) the month and year of manufacture, (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 (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.			
	23.4. Information in the instructions for use The instructions for use shall contain all of the following particulars: (a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2; (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; (c) where applicable, a specification of the clinical benefits to be expected. (d) where applicable, links to the summary of safety and clinical performance referred to in Article 32; (e) the performance characteristics of the device; (f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories; (g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; (h) specifications the user requires to use the device appropriately, e.g. if the device has a	A	ENISO15223-1:2016 EN1041:2008+A1 2013	Label & IFU: CE/MDR-HBZC-03-07&CE/ MDR-HBZC-03-08 a) The points (a), (c) , (k), (n)of Section 23.2 was indicated in IFU, the point (e), (f), (l), and (r) of Section 23.2 is not applicable to the product. b) Intended use was indicated in IFU. c) N/A d) N/A

	measuring function, the degree of accuracy claimed for it; (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; (j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; (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, — 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; (l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; (m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; (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, e.g. signs of material degradation or the maximum number of allowable reuses;			e) See IFU Description of function f) N/A g) Warning and Caution information was described in IFU. h) N/A i) N/A j) N/A k) Usage method was provided in IFU l) N/A m) N/A n) NA, Sigle use. o) N/A

	(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; (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; (q) for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a safe combination, and/or — information on any known restrictions to combinations of devices and equipment; (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; (s) information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, 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			p) N/A. q) N/A r) N/A s) See IFU [Warning].

	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, or temperature, — 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, — 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, — 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 — 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; (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 contraindications, undesirable side-effects and risks relating to overdose; (u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed; (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:			t) N/A u) NA v) See IFU [Disposal].

	— 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; (w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional; (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; (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; (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; (aa) information to be supplied to the patient with an implanted device in accordance with Article 18; (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.			w) The device is easy to operate. x) N/A y) Date of issue was indicated z) N/A aa) N/A ab) N/A

Risk management plan and report

<Product: Shoe Cover >
<Document No.: CE/MDR-HBZC-03-04>
<Date of issue: 2021.02.25 >

Product:	Shoe Cover
Model:	Non woven shoe cover, PE/CPE shoe cover
Procedure:	EN ISO 14971:2019
Conclusion:	All risks associated with the identified hazards have been evaluated considering ISO14971.The overall level of risk of the product is acceptable. After appropriate measures to reduce these risks have been taken, the overall risks (all risks together) have been deemed acceptable versus the benefit of the device.

Issued By	Reviewed By	Approved By	Effective Date
Zhang Yueqiong	Tang Meirong	Ceng Xinquan	2021.02.25

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Document Revision History

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A/0	Initial	Zhang Yueqiong	2021.02.25

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Purpose

In this documentation, we establish, document and maintain throughout the life-cycle an ongoing process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls.

A schematic representation of the risk management process see figure below.

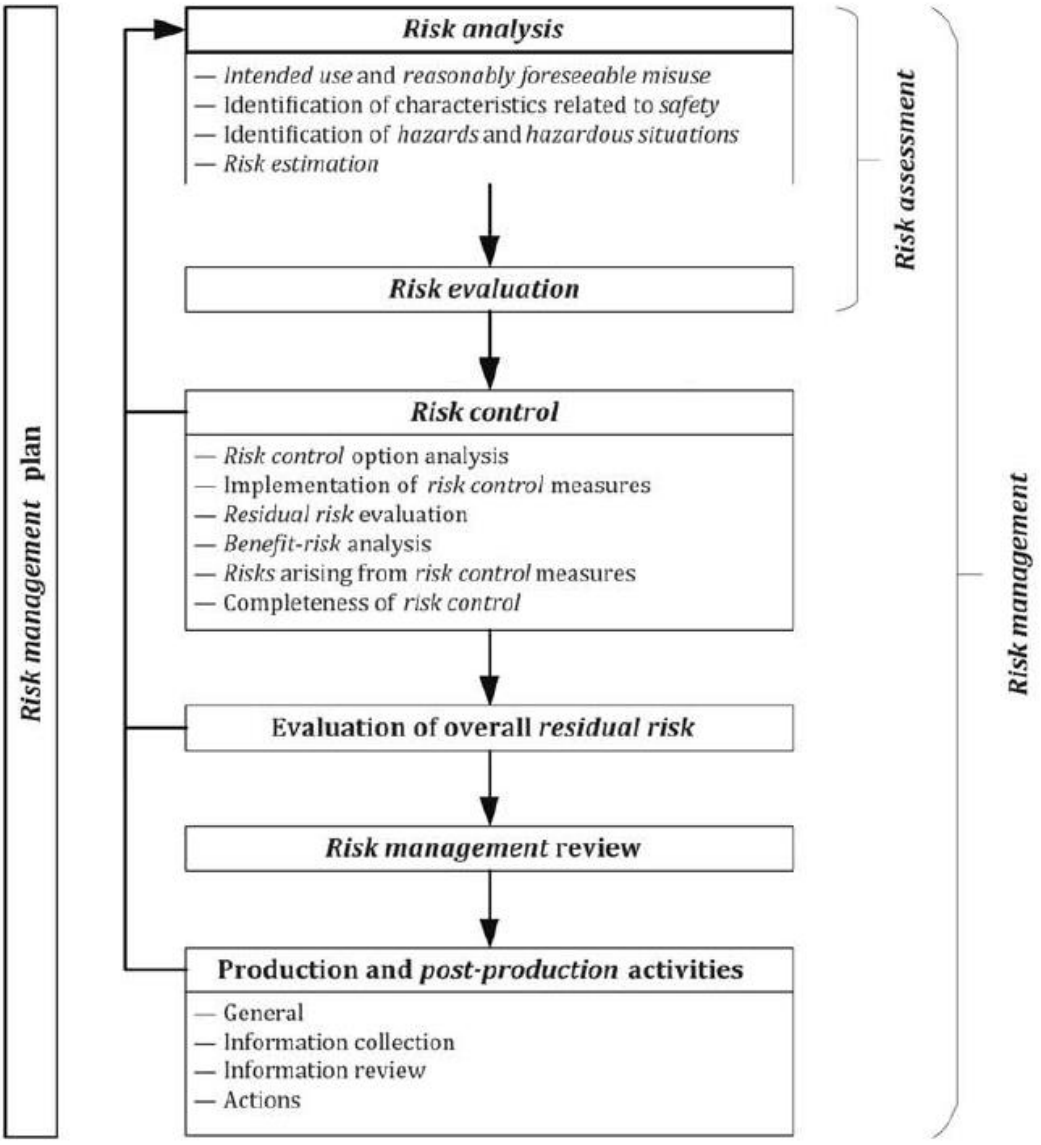


Figure 1 — A schematic representation of the *risk management process*

Chapter One Risk Management Plan

1. Scope and Purpose

The Risk Management Plan has been developed in accordance with the requirements of EN ISO 14971:2019 Medical devices- Application of risk management to medical devices. A schematic representation of the risk management process see figure below. Risk management process will depend on the specific life cycle phase.

This Risk management Plan describe the activities which undertaken to assess the risks associated with the device. It covers the development, production, transportation, servicing and disposal phase for the devices that are covered under this plan. It covers the development, production, transportation, servicing and disposal phase for the devices that are covered under this plan.

2. Device description

2.1 general information

Product name:

Shoe Cover

Intended use:

The product provides general protection. It can be used as general isolation in clinic, ward or laboratory. It is not intended to use in operation room.

Device see figure below:

Figure1 Product picture

Model: Non woven shoe cover, PE/CPE shoe cover
Size: S, M, L, XL

2.2 Material and package information

The Shoe Cover is made of is made of pp nonwoven + Environmental elastic or PE/CPE + Environmental elastic, mainly used for isolation and protection. The product is for single use only and provided non-sterile.

2.3 Package information

100Pcs/bag, 2000Pcs/carton. Also we can pack the quantity and pack system style under the customer’s requirements.

3. Standard List

Regulations:

No.	Serial Number	Title and Description

1	(EU) 2017/745	Medical Device Regulation
2	MEDDEV 2 12-1 Rev:8	Vigilance report form for field safety corrective action report Form Manufacturer's Field Safety Corrective Action Report
3	MEDDEV. 2.7.1 Rev.4	Clinical evaluation: A guide for manufacturers and notified bodies

Standards:

No.	Standard No.	Version	Title
1	EN ISO 14971	2019	Medical Device -Application of Risk Management to Medical Device
2	EN ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
3	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
4	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
5	ENISO 10993-10	2013	Biological Evaluation of Medical Device –Part 10: Irritation and Sensitization Test
6	EN 1041	2008+AI 2013	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices

4. Assignment of responsibilities and authorities

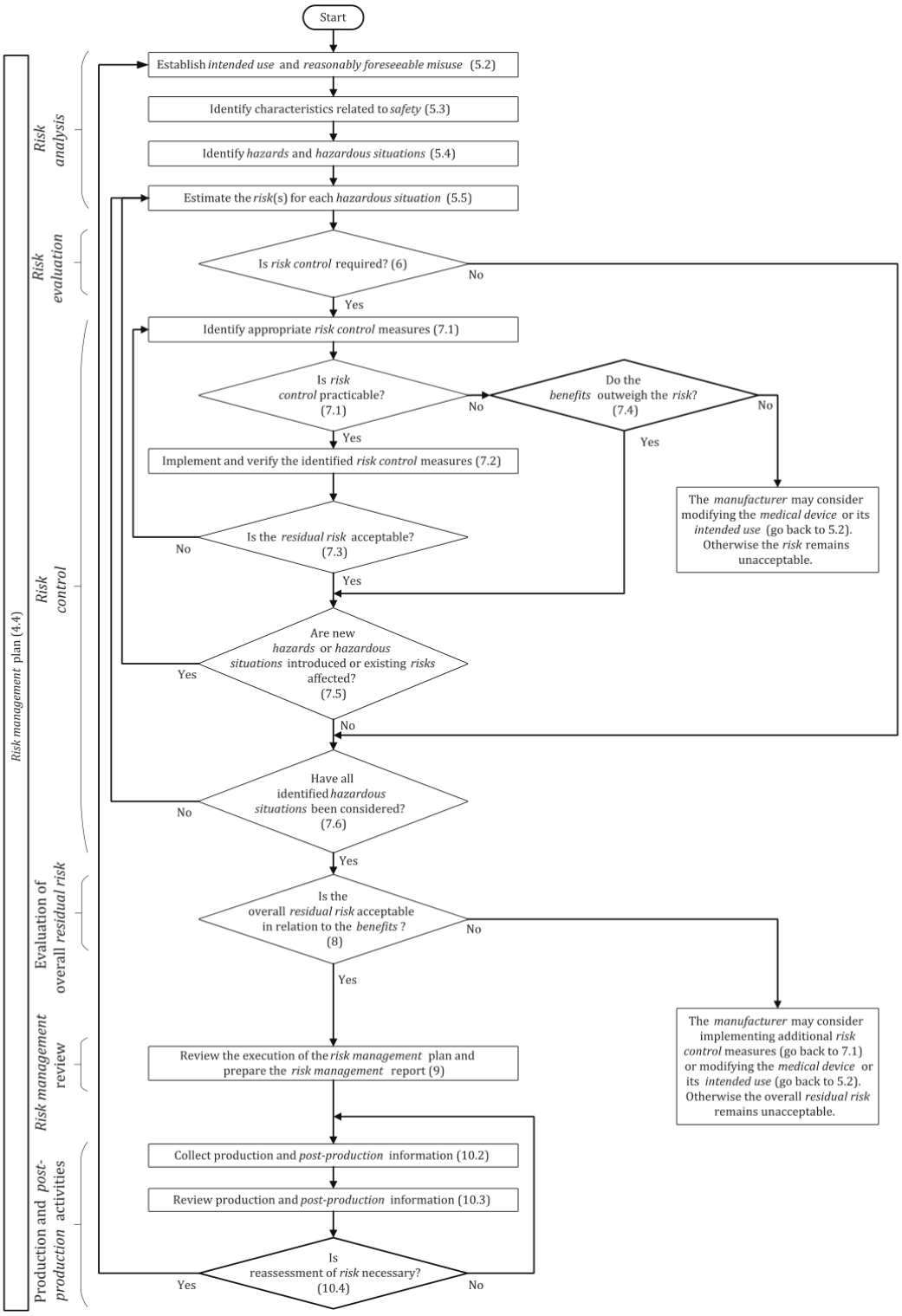
Appoint persons competent on the basis of education, training, skills and experience appropriate to the tasks assigned to them. These persons shall have knowledge of and experience with the medical device or similar medical devices and its use, the technologies involved or the risk management techniques employed. Risk management tasks will be performed by representatives of several functions, each contributing their specialist knowledge.

Name	Department	Position	Responsibility scope
Ceng Xinquan	GM	Risk management team leader	To establish risk management team, risk management planning, directing and coordinating the risk management activity. To ensure that risk management activities conform to the requirements of the risk management, control, and guide the implementation of risk management activities.
Ceng Xinquan	Sales Department	Risk management team member	Responsible for the post-marketing the risk information collection, feedback
Tang Meirong	MR	Risk management team member	Involved in risk analysis, risk evaluation, risk control, comprehensive residual risk evaluation, review the risk management document
Zhang Yueqiong	QA Department	Risk management team member	Involved in risk analysis, risk evaluation, risk control, comprehensive residual risk evaluation, review the risk management document

Tang Meirong	MR	Management representative	Review risk management of the document
Ceng Xinquan	GM	-----	Responsible for risk management of the document for approval

5. Risk Management Process

Risk Management Process will be conducted follow the process below and company Risk Management procedure.



6 Implementation of risk management process

6.1 Step 1: Intended use and identification of characteristics related to the safety of the medical device.

6.1.1 Risk management of life cycle

Risk management is accompanying the overall life cycle process of product, from the input of order form, production, to the output of service, and the evaluation to feedback information system after selling.

The primary risk management is carried out in the design stage. It will put forward requirement to reduce and risk control. In the special stage of developing stage it should validate whether there is new hazard, whether the existent hazard level valuation and valuation of hazard probability is effective, make necessary modification.

Risk management should be commented, the completeness and accuracy should be identified after developing work is finished formal.

Feedback information is not gained from practice in the developing stage. Risk management should be validated again if the feedback of safety problem in the production and using process is gained, and make necessary modification.

6.1.2 Intended use and identification of characteristics related to the safety of the medical device

6.2 Step 2：Identification of known or foreseeable hazards

The hazard “A,B,C_…” sign is used to be designated in the risk management sheet.

Source of information:

The following information can be used in the list of potential hazards:

- Risk analysis report similar product；
- Investigation to developer of product；
- Expert judgment；
- Analysis the report of the foreign department of medical device；
- Study the related measures to reduce risk in the similar product；
- The scene information is gained from the similar product which has been used, service report, complaint and accident record.

The following questions can aid the person in identifying all the characteristics of the medical device that could affect safety. (According to EN ISO 14971:2019 Annex C.2)

6.3 Hazards identification

Hazards identification is provided in ISO 14971:2019 Annex E as a complementary tool to determine Known or foreseeable hazards. In accordance to the definition in this risk management, some contents in the appendix 1 are hazards or only the causes of hazards, so they are not analyzed as hazards or potential reason for hazards.

Each of the contents has description of its correlation to the device, and the circumstances of hazard or hazard causation where such factor shall be considered.

6.4 Risk Evaluation (Step 3)

6.4.1 risk evaluation criterion

1) Qualitative levels of severity

Severity level	Code	Description
Negligible	S1	Inconvenience or temporary discomfort, these do not require any medical treatment.
Minor	S2	Could result in temporary injury not requiring professional medical intervention
Serious	S3	Could result in injury requiring professional medical intervention
Critical	S4	Could result in permanent partial disability, injuries
Catastrophic	S5	Could result in death, or life-threatening injury

2) Probability levels of hazards

Level	Code	Probability of occurrence
Improbable	P1	With a probability of occurrence less than $<10^{-6}$, unlikely to occur, but possible.
Remote	P2	With a probability of occurrence less than 10^{-5} but greater than 10^{-6}, or occurs more than once a product life-cycle
Occasional	P3	With a probability of occurrence less than 10^{-4} but greater than 10^{-5}, or occurs more than once a year
Probable	P4	With a probability of occurrence less than 10^{-3} but greater than 10^{-4}, or occurs more than once a season
Frequent	P5	With a probability of occurrence more than 10^{-3}, or occurs more than once a month

3) Acceptable risk criterion

We made acceptable risk criteria according to the feature of our product and the similar or same device in the markets.

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)					

U: Unacceptable risk A: acceptable risk

6.4.2 Risk Evaluation

The preliminary risk evaluation matrix for the device can be obtained based on below preliminary hazard estimation form.

Preliminary risk evaluation matrix

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)					

6.5 Risk control measures and risk evaluation after taking measures (step 4)

Risk control measures summary and risk evaluation see appendix 2 < risk control measures and risk evaluation after taking measures >

risk evaluation matrix after taking measures

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)					

Above matrix shows that hazards after taking measures are all acceptable.

6.6 residual risk evaluation (Step 5)

After the risk identification and analysis, if there are still residual risks exist. The hazards and actions taken are summarized as follows:

SN	Potential hazards	Causes	Actions

The above risks will not cause harm to patients or operators under the normal production and use. The overall residual risk was detailed in the IFU such as: skilled operation, patients follow the doctor's advice and other safety information.

Specific evaluation:

1) Are there conflicting requirements of risk control of individual risk?

Conclusion:

2) Warning review (are there too many warnings?)

Conclusion:

3) IFU review (are there conflicts or descriptions hard to follow)

Conclusion:

4）Compare with similar products

Conclusion:

5) Expert conclusion

Conclusion:

6.7 Risk /benefit analysis (Step 6)

6.7.1 after all risks control measures have been implemented and verified, all departments consider

whether all comprehensive residual risk caused by the product based on the rule of article 4 of the judge in this plan is acceptable, if the judge is unacceptable, then each department should collect and review the relevant information and documents, to determine whether the intended use of the medical benefit more than comprehensive residual risk, if the evidence to support the medical benefit more than comprehensive conclusion of residual risk, comprehensive residual risk is acceptable, otherwise comprehensive residual risk still is unacceptable.

6.7.2 all departments may refer to some methods to evaluate the comprehensive residual risk.

6.7.3 event tree analysis: to conduct a joint study on individual risks in order to determine whether the comprehensive residual risk is acceptable;

6.7.4 fault tree analysis: the same kind of damage may be caused by the hazard of different probabilities, which can export the combination probability of damage;

6.7.5 comprehensive review of individual risk control measures: the appropriate risk control measures for individual risks may produce conflicting requirements;

6.7.6 review of warnings: individual warnings may provide reduced risk, but excessive warnings may reduce the effect of warnings;

6.7.7 review operation manual: the review of all operating instructions of the product may be inconsistent or difficult to comply with;

6.7.8 comparison of risks: comparing the individual residual risks that have been collated with those of similar existing products to consider the risks in different situations, especially the latest adverse events.

6.7.9 each department shall decide which comprehensive residual risk shall be based on EN ISO 14971:2019 appendix J shall be published, and the evaluation result of the comprehensive residual risk shall be maintained.

6.8 New hazards resulting from situation after take risk control measurements (Step 7)

From Control measures and Risk Evaluation after taking measures, we know there is no new hazards after take risk control measurements.

6.9 Completeness of risk control (Step 8)

Ensure that risks from all identified hazardous situations have been considered and the results of all activity have been recorded.

6.10 Evaluation of overall residual risk acceptability (Step 9)

If the medical benefit outweigh the overall residual risk by using the criteria established former, the overall residual risk are acceptable. The information is showed in accompanying document.

7. Result of risk management (Step 10)

The following list indicates that adopting or not adopting measure will have hazard/reason. Therefore after adopting related measures, there is no unacceptable.

The risk management review group reviews the risk management process by reviewing the product reviews and reviewing the risk management documents.

- the risk management plan has been properly implemented;
- comprehensive residual risk is acceptable;
- the relevant production and post-production information has been obtained by appropriate means;
- all remaining risks are within acceptable limits of risk acceptance criteria, and the benefits outweigh the risks.

Production and after production information acquisition method to see the customer information feedback control program, the board of the customer information feedback control program production and after production information access the suitability and effectiveness of the evaluation, think: this method is suitable and effective, the production

and after production information access can be according to the requirements of the customer information feedback control program, the project risk management, head to the production and after production information management, when necessary, the risk management team to implement the dynamic risk management activities. Since the product has not yet been formally produced, once the production is officially produced, it will collect all kinds of risks in production, and analyze, evaluate, control and update the contents of risk management report again.

Chapter two Risk management Report

1. Summary

This document is a risk management report for the Shoe Cover. All hazards and each potential reason causing the relevant hazard situations have been judged in this document. This document also estimates the severity of harm and the probability of occurrence of the hazards. Risk control measures have been taken to reduce risk, all residual risks have been evaluated according to estimate criteria, overall residuals are considering acceptable. Production and Post-production information collection is planed. After all risk management process, we conclude that the device has benefits of the device outweigh the residue risks.

2. Risk management group

Risk management is carried out by special personnel from many departments. It includes the following members

Name	Department	Position	Responsibility scope
Ceng Xinquan	GM	Risk management team leader	To establish risk management team, risk management planning, directing and coordinating the risk management activity. To ensure that risk management activities conform to the requirements of the risk management, control, and guide the implementation of risk management activities.
Ceng Xinquan	Sales Department	Risk management team member	Responsible for the post-marketing the risk information collection, feedback
Tang Meirong	MR	Risk management team member	Involved in risk analysis, risk evaluation, risk control, comprehensive residual risk evaluation, review the risk management document
Zhang Yueqiong	QA Department	Risk management team member	Involved in risk analysis, risk evaluation, risk control, comprehensive residual risk evaluation, review the risk management document

Tang Meirong	MR	Management representative	Review risk management of the document
Ceng Xinquan	GM	-----	Responsible for risk management of the document for approval

3. Intended use and identification of characteristics related to the safety of the medical device (see user manual)

4. Step 2：Identification of known or foreseeable hazards

The hazard sign is used to be designated in the risk management sheet.

Source of information:

The following information can be used in the list of potential hazard:

- Risk analysis report similar product
- Investigation to developer of product
- Expert judgment
- Analysis the report of the foreign department of medical device
- Study the related measures to reduce risk in the similar product, it often suppose the hazard at first.
- The scene information is gained from the similar product which has been used, service report, complaint and accident record.

The questions (According to EN ISO 14971:2019 Annex C.2) can aid the person in identifying all the characteristics of the medical device that could affect safety refer to Appendix A.

Hazards determination

There list in annex D of EN ISO14971:2019 to be used as auxiliary tool for determination of potential hazards. According to definitions of this risk control, some of the contents are of hazards, while some are only causes of the risks, therefore haven't been analyzed as hazard or causes of the hazards refer to Appendix A.

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

5. Severity valuation of each hazard

Severity valuation of each hazard is judged by the medical expert and the Qualitative identification is given the form of severity.

Severity level	Code	Description
Negligible	S1	Inconvenience or temporary discomfort, these do not require any medical treatment.
Minor	S2	Could result in temporary injury not requiring professional medical intervention

Serious	S3	Could result in injury requiring professional medical intervention
Critical	S4	Could result in permanent partial disability, injuries
Catastrophic	S5	Could result in death, or life-threatening injury

6. Identification to the potential reason of each hazard

All members of group firstly search for the potential reason straight through the special knowledge of every person(seeing Table 2 causes of each hazard)

7. Evaluation to the probability of every reason

The probability of potential reason of hazard should be evaluated. Besides the related information source is:

- Similar product using experience (such as: service statistics data)
- Approved technical regulation (such as: intensity calculation)
- Self-life cycle investigation
- Expert judgment

These estimations are classified into 5 levels by engineering expert (The ratio between number of events and the boot number of all sold similarity products)

Level	Code	Probability of occurrence
Improbable	P1	With a probability of occurrence less than $<10^{-6}$, unlikely to occur, but possible.
Remote	P2	With a probability of occurrence less than 10^{-5} but greater than 10^{-6}, or occurs more than once a product life-cycle
Occasional	P3	With a probability of occurrence less than 10^{-4} but greater than 10^{-5}, or occurs more than once a year
Probable	P4	With a probability of occurrence less than 10^{-3} but greater than 10^{-4}, or occurs more than once a season
Frequent	P5	With a probability of occurrence more than 10^{-3}, or occurs more than once a month

8. Step 3: Risk evaluation（before adopting control measures）

Two risk factors are summed in the first hazard/ reason: severity of hazard and occurring probability, and the related risk. Two “risk areas: Unacceptable area/ Acceptable area ” can be defined in accordance with the suggestion of ENISO14971: 2019 refer to Appendix B.

The preliminary risk evaluation matrix for the device can be obtained based on the above form.

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)					
Probable (P4)		M3 M4 M6			
Occasional (P3)		B13 E9 M1 M2 F2 P10	B1 B2 B4 B6 B7 B9 B14 B15 B16 E14 M9 F4 F6 F7 P3 P4 P5 P6 P7 P8 P9		
Remote (P2)					
Improbable (P1)					

There are 30 hazards exiting red unacceptable areas(U) , which need to take measures to lower risk.

9. Step 4: risk evaluation criterion

We made acceptable risk criteria according to the feature of our product and the similar or same device in the markets.

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	U	U	U	U
Remote (P2)	A	A	U	U	U
Improbable (P1)	A	A	A	A	U

U: Unacceptable risk; A: acceptable risk

10. Step 5 and 6: Adopt risk control measures

If the estimated risk is not acceptable when control measure is not adopted, the control measures of each hazard/ reason must be adopted. If several control measures are drew out, the effectiveness is the result adopting related measures refer to Appendix B.

Then we have got a matrix after taking measure, which shows that hazards after taking measures are all acceptable

Probability of	**Severity level**

occurrence	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)					
Probable (P4)					
Occasional (P3)					
Remote (P2)		M3 M4 M6 B13 E9 M1 M2 F2 P10			
Improbable (P1)			B1 B2 B4 B6 B7 B9 B14 B15 B16 E14 M9 F4 F6 F7 P3 P4 P5 P6 P7 P8 P9		

11. Step 7: Residual risk analysis

As can be seen from the Form 1 the company's risk management review group has identified initial hazards，and these initial hazards are within acceptable range. Through various stages of control of design, procurement, production and delivery, manage raw materials and suppliers of spare parts well. After compiling product instructions and designing labels according to the applicable laws and regulations and standards, the identified risk of this device has dropped to a lower level.

In order to further control the product risk, we technically reassess residual risk. refer to Appendix B.

12 Step 8: Risk /benefit analysis

Risk& benefit analysis was conducted refer to Appendix B. Therefore, total amount of residual individual risk may also be regarded as acceptable.

The residual risks will not cause harm to patients or operators under the normal production and use. The overall residual risk was detailed in the IFU.

13 Step 10: Completeness of risk control

Ensure that risks from all identified hazardous situations have been considered and the results of all activity have been recorded. So we forward evaluate that:

1) Are there conflicting requirements of risk control of individual risk?

Conclusion: conflicting requirements of risk control have not yet been found.

2) Warning review (are there too many warnings?)

Conclusion: warning notes are clear, complying with the standard.

3) IFU review (are there conflicts or descriptions hard to follow)

Conclusion: the IFU conforms to the special safety standards of EN1041 & EN ISO15223-1, and the descriptions related to product safety are clear, easy to understand and easy for users to read.

4）Compare with similar products

Conclusion: The device was compared with the similar product in the market. Their design criteria, raw materials, processing technology, sterilized packaging, disinfection and sterilization methods, usage and intended use are comparable.

5) Expert conclusion

Conclusion: after analyzed the above aspects and fully communicated with the clinical application experts, the risk management review team unanimously believed the overall residual risk of the product is acceptable.

14. Step 11: Evaluation of overall residual risk acceptability

Medical benefit outweight the overall residual risk by using the criteria established former (see appendix B), the overall residual risk are acceptable.

15. Step 12: Result of risk management

The following list indicates that adopting or not adopting measure will have hazard/reason. Therefore, after adopting related measures, there is no unacceptable.

The risk management review group reviews the risk management process by reviewing the product reviews and reviewing the risk management documents.

- the risk management plan has been properly implemented;
- comprehensive residual risk is acceptable;
- the relevant production and post-production information has been obtained by appropriate means;
- all remaining risks are within acceptable limits of risk acceptance criteria, and the benefits outweigh the risks.

16. Step 13 Production and post-production information

Production process information acquisition method please see <Production management procedure>, The suitability and effectiveness of the information obtained from the information provided in <Production management procedure> by the review team, The production process document provided in the management process is appropriate and effective. The information in the production process can be obtained from the production records that are involved in <Production management procedure>. The project risk management person in charge of manage the production process information, if necessary, Risk management team carrying out dynamic risk management. This product has been through the trial, at the same time, the information of production process and all kinds of risks have been collected, and has carried on analysis, appraisal, control.

Post production process information acquisition method please see < customer feedback and satisfaction management procedure. The suitability and effectiveness of the evaluation group for the post production information acquisition mode in < customer feedback and satisfaction management procedure >, The method is suitable and effective. Post production information may be obtained in accordance with the relevant methods in < customer feedback and satisfaction management procedure >, The project risk management person in charge of manage the production process information, if necessary, Risk management team carrying out dynamic risk management.

To review all records of above implementing procedures, to evaluate the aroused risk if exist, and start a new round risk analysis and management.

According to the records of the above implementing procedures, no new risks aroused.

We search and collect information on equivalent product in FDA database. And we search literatures since 2009, we found that all risks are acceptable.

17.Give Information for safety and information about residual risk

The purpose of this step is to provide guidance on how information for safety and can be a risk control measure and residual risk(s) can be disclosed.

Information for safety is the least preferred method of risk control, to be used only when other risk control measures have been exhausted. Information for safety gives instructions on action(s) to take or not to take to avoid a risk.

Disclosure of individual and overall residual risk(s) gives background and relevant information necessary to explain the residual risk so users can proactively take appropriate actions to minimize exposure to the residual risk(s).

18. Risk management review

Item	Review	comments
1	Is there a Risk Management Plan?	Yes, the plan has been issued as well.
2	Has the risk analysis been completed in accordance with plan?	Yes
3	Have all the information gathering from intended use and reasonably foreseeable misuse identified ? Review information gathered.	Yes, the information considered is sufficient and effective.
4	Has hazard identification been completed? Review risk assessment matrix	Yes, all hazards has been considered.
5	Whether Risk reduction implement the regulation as far as possible? Review risk control matrix	Yes, comprehensive measures has been taken.

6	Has all residual risk be evaluated? Check the risk control matrix.	Yes, all residual risk be evaluate the benefit of intended use overweigh the risk.
7	Has a overall residual risk evaluation been undertaken? Review the report and Clinical evaluation report.	Yes, all residual risk have been evaluate in Clinical evaluation report.
8	Has a Risk management Report been issued?	Yes.

19. Conclusion

According to the analysis of the risk, all the risk has been identified and the risks which are none accepted have been controlled by measure taken by the manufacturer. The risk has been managed accordingly.

Appendix 1

Identification of qualitative and quantitative characteristics (Accord to EN ISO14971:2019, cl. 4.2)

Questions		Answer
C.2.1 What is the intended use and how is the medical device to be used?	The product provides general protection. It can be used as general isolation in clinic, ward or laboratory. It is not intended to use in operation room.	
C.2.2 Is the medical device intended to be implanted?		NO.
C.2.3 Is the medical device intended to be in contact with the patient or other persons?		Yes, Contact with wearers skin. **Biological hazards**
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?		Main raw materials for the made of Non-woven fabric in testing, product testing materials, meet the health standards. **Biological hazards**
C.2.5 Is energy delivered to or extracted from the patient?		NO.
C.2.6 Are substances delivered to or extracted from the patient?		NO.
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?		NO. single use
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?		NO.
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?		NO. disposable
C.2.10 Is the medical device intended to modify the patient environment?		NO.
C.2.11 Are measurements taken?		NO.
C.2.12 Is the medical device interpretative?		NO.
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?		NO.
C.2.14 Are there unwanted outputs of energy or substances?		NO.
C.2.15 Is the medical device susceptible to environmental		[Temperature]

influences?	Between –15℃ and 40℃ [Humidity] Below 80% **Malfunction hazards**
C.2.16 Does the medical device influence the environment?	NO.
C.2.17 Are there essential consumables or accessories associated with the medical device?	NO.
C.2.18 Is maintenance or calibration necessary?	NO. disposable
C.2.19 Does the medical device contain software?	NO.
C.2.20 Does the medical device have a restricted shelf-life?	YES. 2 years **Biological hazards, information hazards**
C.2.21 Are there any delayed or long-term use effects?	No
C.2.22 To what mechanical forces will the medical device be subjected?	NO.
C.2.23 What determines the lifetime of the medical device?	Material performance, **Biological hazards, information hazards, function hazards**
C.2.24 Is the medical device intended for single use?	YES. Single use. **Biological hazards, information hazards, function hazards**
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	Yes, Never touch the front of the product when removing. Placed straight into a bin once worn. Never share your product with another. **Biological hazards, information hazards**
C.2.26 Does installation or use of the medical device require special training or special skills?	NO.
C.2.27 How will information for safe use be provided?	Label and Instruction for use. **information hazards, function hazards**

C.2.28 Will new manufacturing processes need to be established or introduced?	NO.
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface? C.2.29.1 Can the user interface design features contribute to use error?	NO.
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	NO.
C.2.29.3 Does the medical device have connecting parts or accessories?	NO.
C.2.29.4 Does the medical device have a control interface?	NO.
C.2.29.5 Does the medical device display information?	NO.
C.2.29.6 Is the medical device controlled by a menu?	NO.
C.2.29.7 Will the medical device be used by persons with special needs?	NO.
C.2.29.8 Can the user interface be used to initiate user actions?	NO.
C.2.30 Does the medical device use an alarm system?	NO.
C.2.31 In what way(s) might the medical device be deliberately misused?	NO.
C.2.32 Does the medical device hold data critical to patient care?	NO.
C.2.33 Is the medical device intended to be mobile or portable?	No.
C.2.34 Does the use of the medical device depend on essential performance?	NO.

Appendix B

No.	Hazard		Risk Evaluation			RRM	Evidence	Risk Evaluation			NH	RL
	General	Identify hazards	S	P	RL	Risk Reduction Measure		S	P	RL		
E.1 Energy Hazards												
1	Line voltage	N/A										
2	Leakage current	N/A										
3	Electric fields	N/A										
4	Magnetic fields	N/A										
5	Ionizing radiation	N/A										
6	Non-ionizing radiation	N/A										
7	High temperature	N/A										
8	Low temperature	N/A										
9	Gravity falling	N/A										
10	Suspended masses	N/A										
11	Vibration	N/A										
12	Stored energy	N/A										

13	Moving parts	N/A											
14	Torsion, shear and tensile force	N/A											
15	Moving and positioning of patient	N/A											
16	Ultrasonic energy	N/A											
17	Infrasound energy	N/A											
18	Sound	N/A											
19	High pressure fluid injection	N/A											
E.2 Biological and Chemical Hazards													
1	Bacteria	A, Patient may have a bacterial infection if did not use the product properly, the package of	3	3	NAC	1. Indicate to users in the Instruction for Use how to use the product and indicate the user not to use the product if the package damaged. And indicate user not to reuse the product.	1.Instruction for use 2.Product performance test report 3. Biocompatibility Test Report	3	1	AC	No	AC

		blanket is damaged or re-use the product.				2.Ensure product quality by strictly follow the QMS						
2	Viruses	A, Patient may have a bacterial infection if did not use the product properly or re-use the product.	3	3	NAC	1. Indicate to users in the Instruction for Use how to use the product and indicate the user not to use the product id the package damaged 2.Ensure product quality by strictly follow the QMS	1.Instruction for Use 2.Product performance test report 3.Biocompatibility Test Report	3	1	AC	No	AC
3	Other agents (e.g. prions)	N/A										
4	Re- or cross-infection	A, Patient may got infection if the product were re-used	3	3	NAC	Indicate to users in the Instruction for Use do not re-use the product	Instruction for Use	3	1	AC	No	AC
5	Acids or alkalis	N/A										
6	Residues	N/A										
7	Contaminates	N/A										

8	additives or processing aids	N/A										
9	cleaning, disinfecting or testing agent	N/A										
10	Degradation products	N/A										
11	medical gasses	N/A										
12	Anaesthetic products	N/A										
13	Toxicity of chemical Constituents	A, the product may cause the user uncomfortable if the material is not meet the safety requirements.	2	3	R	Single use and raw material control	Instruction for Use and raw material inspection report.	2	2	AC	No	AC
14	Bio-incompatibility	A, The product may cause the user uncomfortable	3	3	NAC	Choose raw materials meeting the requirements	Biocompatibility Test Report	3	1	AC	No	AC

		if the material is not meet the safety requirements.											
15	Allergenicity	N/A											
16	irritancy	A, The product may cause the user uncomfortable if the material is not meet the safety requirements.	3	3	NAC	Choose raw materials meeting the requirements	Biocompatibility Test Report	3	1	AC	No	AC
17	Pyrogenicity	A, The product may cause the user uncomfortable is not meet the safety requirements.	3	3	NAC	Choose raw materials meeting the requirements	Biocompatibility Test Report	3	1	AC	No	AC
E.3 Environmental hazards and contributory factors													

1	electricity	N/A											
2	Pressure	N/A											
3	radiation	N/A											
4	volume	N/A											
5	Susceptibility to electromagnetic interference	N/A											
6	Emissions of electromagnetic interference	N/A											
7	Inadequate supply of power	N/A											
8	inadequate supply of coolant	N/A											
9	Storage or operation outside prescribed environmental conditions	The product can not reach the intended use, or the product package will be damaged	2	3	R	1.Indicate the distributor or use to store the product by strictly follow the user manual. 2.Control storage / operation process	IFU; Warehouse management practices	2	2	AC	No	AC
10	Incompatibility	N/A											

	with other devices											
11	Accidental mechanical damage	N/A										
12	corrosions	N/A										
13	degradation	N/A										
14	contamination	N/A										
E.4. Hazards related to the use of the device and contributory factors												
1	Inadequate labeling	A, the inadequate labeling may cause misuse or use error	2	3	R	Strengthen amending the label for warning	Refer to label& Instruction for Use	2	2	AC	No	AC
2	Inadequate operating instructions	A, the inadequate operating instructions may cause misuse	2	3	R	Strengthen amending the operating instructions	Instruction for Use	2	2	AC	No	AC
3	Use by unskilled/untrained personnel	A The device may be	2	4	NAC	1.To strengthen pre-use checks 2.Indicate the user how	Instruction for Use	2	2	AC	No	AC

		damaged or hurt patient				to use the product in the user manual.						
4	Reasonably foreseeable misuse	A, The device can reach its intended use.	2	4	NAC	To strengthen pre-use checks and indicate the cautions in the user manual.	Instruction for Use	2	2	AC	No	AC
5	Insufficient warning of side effects	N/A										
6	Inadequate warning of hazards likely with re-use of single use devices	A, Improper operation and hurt the patient	2	4	NAC	Indicate the users that the product is a single use device.	Label	2	2	AC	No	AC
7	Incorrect measurement and other metrological aspects	N/A										
8	Incompatibility with consumables/a	N/A										

	ccessories/other devices											
9	sharp edges or points	N/A										
E.5	**Inappropriate, inadequate or over-complicated user interface (man/machine communication)**											
1	Mistakes and judgement errors	N/A										
2	Lapses and cognitive recall errors	N/A										
3	Attentional failure	N/A										
4	Violation or abbreviation of instructions, procedures, etc.,	N/A										
5	Complex or confusing control system	N/A										
6	Ambiguous or unclear device	N/A										

	state											
7	Ambiguous or unclear presentation of settings, measurements or other information	N/A										
8	Mispresentation of results	N/A										
9	Insufficient visibility, audibility or tactility	N/A										
10	Poor mapping of controls to action, or of displayed information to actual state	N/A										
11	Controversial modes or mappings as	N/A										

	compared to existing equipment											
E.6. Hazards arising from functional failure, maintenance and ageing												
1	Erroneous data transfer	N/A										
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	The device may not work well if lack of inadequate functional checks	2	3	R	1.indicate the use instructions in the user manual; 2. Indicate the user that the product is a single use product.	Instruction for Use	2	2	AC	No	AC
3	Inadequate maintenance	NA										
4	Lack of adequate determination of end of device	NA										

	life											
5	Loss of electrical / mechanical integrity	NA										
6	Inadequate packaging(contamination and /or deterioration of the device)	The lifetime of the device may be reduced or the product package may be damaged.	3	2	R	1.Package the product by strictly follow the QMS 2.Indicate the user do not use the product if the package damaged.	1.Factory inspection records, 2. Instruction for Use	3	1	AC	No	AC
7	re-use and / or Improper re-use	N/A										
8	Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical	N/A										

	conductivity) as a result of repeated use.											
E.7 Production and post-production information（Foresee）												
1	Inadequate of designing parameters	N/A										
2	Inadequate of operating parameters	N/A										
3	Inadequate of performance requirements	A, product quality will be deteriorated	3	2	R	Package the product by strictly follow the QMS	Factory inspection records, Product performance test report	3	1	AC	No	AC
4	Insufficient control of changes to manufacturing processes	A, product quality will be deteriorated	3	2	R	Control the manufacturing processes by strictly follow the QMS	Quality Procedure	3	1	AC	No	AC
5	Insufficient control of materials/mater	A, product quality will be deteriorated	3	2	R	Chose the material which meet the requirement.	1.Biocompatibility Test Report 2.Incoming material	3	1	AC	No	AC

	ials compatibility information	or hurt patient					inspection report.					
6	Insufficient control of manufacturing processes	A, product quality will be deteriorated	3	2	R	Control the manufacturing processes by strictly follow the QMS	Quality Procedure	3	1	AC	No	AC
7	Insufficient control of subcontractors	A, product quality will be deteriorated or hurt patient	3	2	R	Chose the material which meet the requirement.	1.Biocompatibility Test Report 2.Incoming material inspection report.	3	1	AC	No	AC
8	Lack of, or inadequate specification for, validated procedures for cleaning, disinfection and sterilization	NA										
9	Inadequate conduct of cleaning,	NA										

	disinfection and sterilization											
10	Inadequate collection post-product information	A, the product did not satisfied by the customer or could meet the requirement	2	3	R	collect post-product information according to QMS	Quality Procedure	2	2	AC	No	AC

Clinical Evaluation Report

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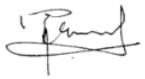
Signature		**Signature**		**Signature**	

Product name: Shoe Cover

Classification of product: I, according to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

Model: Non woven shoe cover, PE/CPE shoe cover

Manufacture: Hubei Zhencheng Nonwoven Products Co., Ltd.

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Name	**Curriculum Vitae**
Sun Jinfeng	1. Essential information Name： Sun Jinfeng Birthday 1972-01-26 Gender：Male Healthy：Good 2. Education & Qualification **Bachelor of Clinical Medicine** Medical device quality management system chief auditor CCAA Registered QMS Senior Auditor National Registered Medicine Intermediate Attending Physician 3. Honors -For three consecutive years (2013, 2014, 2015) selected CCAA good certification case exchanging, and it is the only case of medical equipment certification. -The case of JS Medical Instrument Co., Ltd was awarded excellent case of Shanghai certification association. 4. Experience -14 years of medical equipment industry consulting and auditing related work experience, consulting and reviewing hundreds of medical device related enterprises. -**More than 10 years of hospital work experience, familiar with the clinical use of medical equipment knowledge, medical equipment clinical use requirements have a certain grasp.** 2009.12- Present As a senior manager of ISO9001/13485 quality management system -The main auditor of the 13485 project has rich experience in the audit of medical enterprises and has audited hundreds of enterprises related to medical devices. -Have a deep background in ISO13485 system certification audit work, can play and perform the ISO13485 quality management system, have strong practical experience in medical device industry management system, familiar with the laws and regulations of medical equipment industry, and familiar with the clinical implementation of medical equipment industry, and from the audit

	process has accumulated some experience. 2004.11-2009.11 As a senior auditor of ISO9001/13485/14001 quality management system works in Shanghai JS Certification Co., Ltd. - Mainly engaged in ISO9001, 14001 quality management system audit work - To play company management system, responsible for medical development and tracking project. 2003.3-2004.9 Shanghai Exhibition Management Consulting Company ISO9001/ISO14001/IOS 13485 consultants - Mainly to do the ISO9000/14001/13485 management consulting work, especially in the field of medical equipment industry has a wealth of experience. - The consulting firms involved in trade, chemical industry, medical equipment manufacturing industry, etc. 1990.7-2003.1 As a Physician, party and government office director works in the first hospital of Laohekou, Hubei Province. -Mainly to do the physician and administrative work, the pharmaceutical industry and management work has a wealth of experience. -Familiar with the clinical use of medical equipment knowledge, the clinical use of medical devices has a certain grasp of the requirements.
Tina Cui	1. Essential Information: Name: Tina Cui Gender: Female Date of birth: November,1984 Education: Bachelor Work Experience: more than 10 years experience on medical device regulation in certification body and consulting organization. 2. Education: 2003.02-2006.10 Bachelor of International and Global Studies(International Business) 3. Working Experiences: **2018- Present,** Act as the technical consultant, Consulting for many medical enterprises about CE& ISO13485&ISO9001 and passed the TUV/BSI audit. Training Experiences 2008- IRCA certified auditor training course - QMS9001,13485&product assessor 2017/09, Regulation 2017/745 on Medical devices(MDR) training course,

	Clinical Evaluation of MEDDEV.2.7/1 REV.4 training course, provided by SGS. 2017/08, Regulation 2017/746 on In-vitro Diagnostic Medical devices(IVDR) training(include ISO14971 standard), provided by TUV SUD. 2017.08 ISO13485: 2016 training course, provided by TUV SUD. 2018.11.29-30 EN ISO14971:2012 training course, provided by BSI.
Raymond Luo	From 2004.3 to present, get more than 10 years' experience on the medical device global regulation compliance in global famous certification body and consulting organization. **Major: Biological engineering** 2004.3 to 2015.3 Production certification director and the manager of the international business unit, manage the business of the global product certification including CE marking and all the certification business in Asia Pacific, which covers 14 countries besides China. 2015.3 to Present Act as the technical manager of SUNGO Technical Service Inc., responsible for the medical device compliance consulting, covers US and EU regulations.

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Executive summary

This clinical evaluation report presents the clinical evaluation of Shoe Cover which is used in hospital, clinic, beauty salon, food production industry, building, purification workshop or clean room, outdoors to keep from external harmful material.

Shoe Cover manufactured by Hubei Zhencheng Nonwoven Products Co., Ltd., is made of non-woven and manufactured based on quality management system ISO13485:2016.

The clinical evaluation is conducted by collecting and analyzing clinical literature of the similar device of Shoe Cover search from PubMed, ScienceDirect, China CNKI database and other literature database list in section 4. PMS data held by manufacture and PMS data of the similar device from FDA Manufacturer and User Facility Device Experience (MAUDE) database.

The clinical data analysis concludes that the Shoe Cover complication rates and risks related to the devices remain continuously low and acceptable. No clinically relevant change is detected over time, and no new health or safety risks, no new side effects have been discovered during this evaluation. Anticipated residual risks may occur, but the number is low.

As a result of this clinical evaluation, the evidence provided demonstrates the safety and performance of Shoe Cover in their product-specific indications as describable in Instructions for Use, also conformity with the EU General Safety and Performance Requirements.

1. Scope of the clinical evaluation

The objective of this clinical evaluation is to identify, select, review and assess all available clinically relevant data of Shoe Cover.

Conformity assessment with the Medical Devices Regulation (EU) 2017/745 requires a medical device manufacturer to demonstrate that the claims made in relation to the device’s safety and performance, under the normal conditions of its use, are attainable. Generally, this requires clinical data, but evidence of the satisfactory clinical safety and performance of a device may be provided in the form of a critical evaluation of published and/or unpublished data on clinical experience with the device, or on a similar device to which equivalence can be demonstrated. This clinical evaluation is submitted to the MDR (EU) 2017/745.

Based on the General Safety and Performance Requirements and the residual risk findings from the Shoe Cover risk analysis, the scope of this clinical evaluation comes from the intended performance and clinical residual risks in the risk from the intended

performance and clinical residual risks in the risk analysis of these products.

2. Device description

Shoe Cover is used in hospital, clinic, beauty salon, purification workshop or clean room to keep from external harmful material.

This device is a disposable product, suitable for the health care of the wearer in the general medical environment and the general care in public health places to prevent unwanted dust, liquid and other substance.

Shoe Cover is going to contact with the intact skin of the user, and it has been tested according to related compatibility standards including ISO 10993-1:2018, EN ISO10993-5： 2009 and EN ISO 10993-10:2013, please refer to Annex 3< biocompatibility test report>.

The product images and specification of Shoe Cover are shown as below.

The Shoe Cover product image is shown as below.

Figure1 Product picture

Intended Use
The product provides general protection. It can be used as general isolation in clinic, ward or laboratory. It is not intended to use in operation room.

Model
Non woven shoe cover, PE/CPE shoe cover

Size
S, M, L, XL

Packaging
The products were generally packed 100 pcs per polybag, and 2000 pcs per carton. Also we can pack the quantity and pack system style under the customer’s requirements.

Storage
The product should be stored in a cool, dry, well ventlated and clean environment. Keep away from direct sunlight and heat source.

How to use the device
Wear on feet or shoes directly.

Shelf Life
2 years

Caution
1.This product is for one-time use only.
2.It shall be properly treated as required and followed the local laws and regulations after use.
3.Never share your product with others.
4.Wash your hands thoroughly upon removal of the product.
5.Use with caution when you are allergic to nonwoven fabrics.

Warning
1. Once the Shoe Cover get dirty and cannot provide further protection, please change another new one.
2. Only for single use.

Disposal
Please dispose the product after use to comply with local regulation.

Harmonized standards

No.	Standard No.	Version	Title
1	(EU) 2017/745	2017	Medical Device Regulation
2	EN ISO 14971	2019	Medical Device -Application of Risk Management to Medical Device
3	EN ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
4	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
6	EN ISO 10993-10	2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
7	EN 1041	2008+A 1:2013	Terminology, Symbols and Information Related to Medical Devices –Information Provided by

			Manufacturers of Medical Devices

Table 2. Reference Guidance

Item.	Guidance	Title
1	MEDDEV 2.7.1 rev.4 (2016)	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
2	MEDDEV 2.12-2 rev 2 (2012)	Guidelines on post market clinical follow up
3	GHTF SG5/N2R8	Clinical Evaluation

3. Clinical background, current knowledge, state of the art

Background:

To prevent the spread of the disease, we usually take control measures to vaccinate susceptible people or isolate infected people to reduce the incidence of disease and infectious. Shoe Cover is one of the important tool of isolation, and the medical staff in hospital using isolation or operating room (or) shoes, much is made of plastic film, which is easy to broken, do not breathe freely again, and the shoe is too low, can't wrap the socks and opening medical staff together in isolation, so the medical staff are more likely to get bacteria, also easy to the dirt and dust on the shoes and trousers to the isolation zone, such as pollution. Now, there many cover shoes made of non-woven, and they have been widely used in hospital, food industry. There are many advantages of the shoes cover, such as (1) Good isolation: the upper of the Shoe Cover of the utility model wraps all socks and trouser legs of the medical personnel, achieving the function of sealing and isolation. The sole is a waterproof cloth, which has a good waterproof effect and prevents the water stains on the ground from being soaked in shoes, socks and trouser legs through the Shoe Cover, so as to avoid pollution. (2) abrasion resistance: waterproof. The cloth shoe sole has anti-corrosion, anti-tear, anti-peel performance, not easy to wear, in clinical practice is very strong, reduce the inconvenience caused by Shoe Cover damage;(3) good ventilation: because the upper is made of medical non-woven fabric, it has good air permeability, which solves the problem of airtight plastic film Shoe Cover;(4) environmental protection: the Shoe Cover is made of medical non-woven cloth and waterproof cloth, and its components are easy to degrade.

Current Knowledge, State of art:

The non-woven fabric production technology is different from the traditional textile technology, and the spinning process is not required in the textile process. The textile technology is similar to the papermaking technology, also known as non-woven fabric.

The appearance and some aspects of the non-woven fabric are similar to those of the cloth, but it is not intertwined one by one, but is physically bonded together, so it is called a non-woven fabric. Non-woven fabrics are generally classified into polypropylene and polyester. Nylon, etc., can also be divided into disposable and durable non-woven fabrics. Non-woven fabrics are not able to draw one thread at the time of use. They are environmentally friendly, breathable, light, moisture-proof, durable and many other modern meanings, and are widely used in disposable products, non-woven puzzles, hardcover flour bags.

The non-woven fabric industry is considered to be a sunrise industry in the 21st century and is currently developing rapidly. According to China Industrial Textiles Industry Association (CNITA), the total output of China's non-woven fabrics is increasing year by year, with an average annual growth rate of more than 15%, and the total output is now the highest in Asia. At present, synthetic fiber occupies a significant advantage in the production of non-woven fabrics. Non-woven fabrics are concentrated in high-tech penetration and new materials. In terms of use, it is widely used in construction, automobile, clothing, medical, aerospace, environmental protection and other industries. At present, the application in sanitary products is expanding, and the medical textiles, vehicle textiles, footwear and artificial leather market are also showing new weather. Non-woven fabrics have High value-added and high-efficiency competitive advantage.

At present, non-woven fabrics have gradually become emerging industries in the international and domestic markets. China's non-woven fabric production has achieved rapid development, but the economy is still developing, people's needs are increasing, and the future development trend of China is expected. We should open up a broader market, develop and develop first-class equipment and equipment, and produce more high-quality, high-standard, high-grade products, which will further develop the non-woven fabric industry.

4. Identification of relevant clinical data

There are several types of clinical data which are clinical literature of similar device, PMS data of the propose device from manufacture including sales and complaints data, customer feedback, adverse event reports, the medical device reporting data and recall data of similar device of similar device.

4.1 Literature Data

Literature from some databases are used to evaluate the safety and performance of the predicate or similar device which are placed to the market.

4.2 PMS data generated and held by Manufacture

The propose device Shoe Cover has been sold for many years. PMS data including customer feedback, customer complain, adverse event, recall and corrective actions will be analyzed in this evaluation.

4.3 PMS data of similar device

The Shoe Cover has been widely used in many industries, such as hospital, food industry, we will search the adverse event, recall, corrective action of the similar device for a reference for the clinical safety of the propose device.

4.4 Literature search plan

4.4. 1 Literature search database

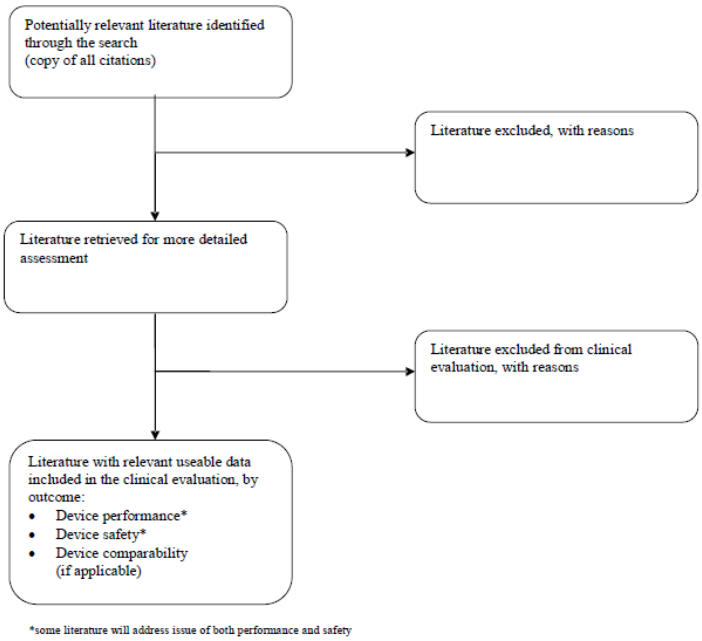
The databases used for literature search are shown as below

- PubMed
- ScienceDirect
- CNKI

We used “Shoe Cover” as key word to search on the database list above and select the relevant literature for clinical evaluation.

4.4.2 Literature selection criteria

The literature selection criteria process is as follow:



We select the relevant literature according to the device discussed in the article, if the

device is similar to the propose device, we will choose that literature for evaluation. If the device has similar intended use, the same work mechanism to the propose device, the device will be deemed as the similar device.

4.4.3 Literature exclusion criteria

We will review all articles' title and/or abstracts, if the article did not include Shoe Cover, non-woven fabric or the article in question did not examine humans; or no clinical data was available. The article would be excluded. Besides, we will review all the titles and abstracts of all the relevant literature to exclude the same literature.

5.Analysis of Clinical Data

5.1 Analysis of Literature

We use "Shoe Cover" as key word to search relevant literature in the database listed in section 4.4.1 and search time is 2000-2020. Take the ScienceDirect database for example, when we enter key word "Shoe Cover",18912 literature are found in ScienceDirect, then we review the relevance of literature and download 8 relevant literature for review and completely review the literature, finally 2 literature are chose for evaluation. The search result is as below.

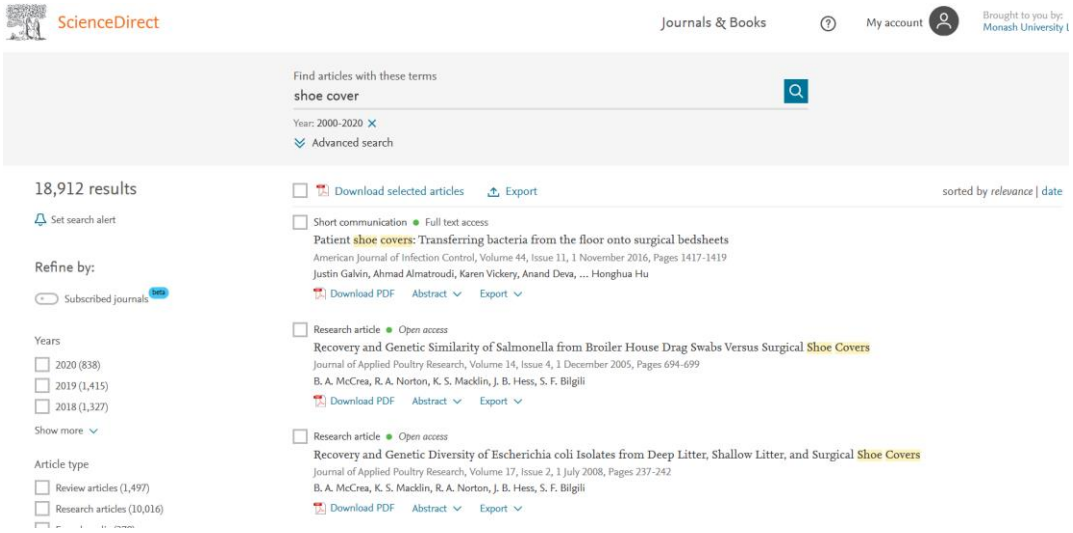


Figure2 Search Result in ScienceDirect

The relevant literature and the literature used for clinical evaluation of all the databases we searched are shown in table below.

Table3 Literature Collection in different Database

Item	Database	Search Date	Search term	Search Period	Total Literature	Relevant Literature	Literature for Clinical Evaluation

1	PubMed	12/02/2021	Shoe Cover	2000-2020	143	10	2
2	Science Direct	12/02/2021		2000-2020	18912	8	2
3	CNKI	12/02/2021		Not Limited	132	5	3

Base on the Literature search result above, there are 7 literatures are used in this clinical evaluation. Literature analysis is shown in the table below.

Table4 Literature Analysis

Item	Literature	Author& Publication	Abstract
1	Patient Shoe Covers: Transferring bacteria from the floor onto surgical bedsheets	Justin Galvin BSc a, Ahmad Almatroudi MPH a, Karen Vickery PhD a, Anand Deva MBBS a, Lillian Kelly Oliveira Lopes MN a,b, Dayane de Melo Costa MN a,b, Honghua Hu PhD. American Journal of Infection Control (2016)	Forty disposable medical Shoe Covers were briefly exposed to the surgical floor and were found contaminated by a large number of bacteria. This study also demonstrated live bacteria, including pathogens attached to contaminated Shoe Covers, can be subsequently transferred to surgical bedsheets. We suggest an infection control policy should be considered to prevent patients returning to their bed with contaminated disposable Shoe Covers.
2	To determine the effect of wearing Shoe Covers by medical staff and visitors on infection rates, mortality	Ali Z, Qadeer A, Akhtar A. Pak J Med Sci 2014;30(2):272-275.	Objective: Intensive Care Units (ICUs) experience higher infection rates due to the severity of illness and frequent use of invasive devices. Use of personal protective equipment reduces the risk of acquiring an infection. This study has been conducted to determine the role of using Shoe Covers by medical staff and visitors on infection rates, mortality and length of stay in ICU. Methods: It is a descriptive study, performed in Shifa International Hospital, Islamabad from January 2012 to July 2012. The rates of infection (by checking patients for common ICU pathogens), mortality and

	and length of stay in Intensive Care Unit		length of stay of patients admitted in MICU and SICU from January 2012 to March 2012 were measured. Use of Shoe Covers was abandoned during this period. The same parameters were measured for the patients admitted from May, 2012 to July, 2012; the period during which Shoe Covers were strictly used by all the staff members and visitors. The data was then analyzed and compared using chi-square test with significance value at $p < 0.05$. Results: A total of 1151 patients were studied in 06 months period. Among the two groups of patients, managed with and without using Shoe Covers in ICU, statistically significant decrease was seen in terms of length of ICU stay(as P value is less than 0.05) in patients managed in duration of Shoe Covers. However, the time period in which Shoe Covers were used the infections with three common ICU pathogens MRSA, VRE and acine to bacter were statistically significant more than the periods in which Shoe Covers were not used. There was no significant difference in mortality for both groups (P value = 0.146). Conclusion: Use of Shoe Covers in critical care area is not helpful in preventing infections of common ICU pathogens and length of stay in ICU patients; nor has it decreased the mortality.
3	Manufacture and application of disposable medical isolation Shoe Cover	Wang Aifang, Journal of nursing education, vol. 27, No. 11, June 2012	In order to prevent the spread of disease, we usually take control measures to prevent vaccination of susceptible populations or to isolate infected people to reduce the incidence and contagiousness of the disease. Isolation shoes are also one of the important isolation tools. Currently, the isolation shoes used by medical staff in the hospital isolation area or operating room are mostly made of plastic film, which is easy to break and airtight, and the upper is too low to be medical. The socks and pants of the personnel are wrapped together for isolation, so that medical personnel are easily infected with germs, and it is easy to bring dirt, dust and the like on the shoes and the trousers into the isolation area, causing pollution. To this end, we have created a new type of disposable medical isolation Shoe Cover. Compared with the prior art, the new isolated Shoe Cover not only has good isolation, but also can wrap the socks

			and trousers of the medical staff to achieve the function of sealing and isolation, and has good waterproof effect, wear resistance, corrosion resistance and tear resistance. Crack, anti-peeling performance, not easy to wear, good ventilation, solve the problem of plastic film Shoe Cover is not breathable.
4	Recovery and Genetic Similarity of Salmonella from Broiler House Drag Swabs Versus Surgical Shoe Covers	B. A. McCrea, R. A. Norton, K. S. Macklin, J. B. Hess, and S. F. Bilgili1，2005 J. Appl. Poult. Res. 14:694–699	Reducing the contamination of poultry houses requires adequate sampling of the environment. Sampling regimens that assess the Salmonella status of broilers prior to processing can be used to identify and process negative flocks first. The current study was designed to evaluate the efficacy of surgical Shoe Covers vs. drag swabs in the recovery of Salmonella from poultry house litter. Current methods of determining the colonization status of a flock include drag swabs of the litter surface. This method requires significant time and labor in drag swab assembly preparation. The time and cost involved with drag swab assembly, sterilization, and use decreases the likelihood that the number of samples needed to adequately assess the health of a flock will be taken. A simple solution to the sampling problem is the use of surgical Shoe Covers. Our results indicate that surgical Shoe Covers are more effective (12.5%) in recovering Salmonella from an infected flock than drag swabs (2.1%). Three Salmonella serotypes were recovered with surgical Shoe Covers, whereas only one serotype was recovered with drag swabs. The Salmonella serotypes from drag swabs that matched the serotypes from surgical Shoe Covers were genetically identical. Poultry supervisors often travel to farms to assess a flock prior to processing, and to aid in this evaluation, surgical Shoe Covers may be worn over disposable plastic boots as supervisors walk through the house. Surgical Shoe Covers cost $0.70/pair and may be kept in vehicles along with disposable plastic boots.
5	Recovery and Genetic Diversity of Escherichia coli	B. A. McCrea,*1 K. S. Macklin,† R. A. Norton,† J. B. Hess,† and	Litter is a common source of infectious agents in poultry production environments. Typical sampling methods only examine bacteria on the surface; however, bacteria recovered with these methods may not be representative of the population in the litter. To test this hypothesis, both shallow (top 2 in.) and deep

	Isolates from Deep Litter, Shallow Litter, and Surgical Shoe Covers	S. F. Bilgili，2008 J. Appl. Poult. Res. 17:237–242 doi:10.3382/japr.2007-00067	(bottom 2 in.) litter samples were taken and compared with a surface sampling method (i.e., surgical Shoe Covers). Escherichia coli isolates were recovered from all 3 sample types and examined using an automated ribotyping system to determine the genetic diversity of the isolates. Twenty-six unique E. coli strains were recovered from the 3 different sampling methods. There was no correlation among strains between visit age, house, flock, or farm and ribogroups. Based upon the patterns of E. coli recovery among the different sample types, our results suggest that surface sampling methods are equally capable of recovering common isolates from the litter. Surgical Shoe Covers were easy to use, provided the same core population of isolates, and were comparable to shallow litter in the number of strains recovered.
6	The effect of the disposable shoes for the ICU infection control	Jia Jianxia, Zhao Xiuli, Jia Huixue et al., Chinese Nursing Management, 2009，9(1)：69-70	Objective：This study aimed to investigate the effect of the disposable shoes for the ICU infection control. Methods：According to the disinfection criterial atmosphere and object surface were checked for the bacterium group for 10days. Results: The bacterium groups with no disposable shoes were lower that with disposable shoes, which showed a statistic and significant difference(P<0.05.). The pass rate of the object surface bacterium groups of the two groups had no statistic and significant difference(P<0.05). Conclusion: The disposable shoes could not improve the cleanness of the atmosphere and object surface in ICU.
7	Disposable Over-shoes Using for Nosocomial Infection Control in Intensive Care Unit	JIA Jian-xia , JIA Hui-x ue , ZHAO Xiu-li , ZHAO Yan-chun , GU Xiu-e , SUN Li-ying , REN Jun-hong , SONG Li-hong , LI Liu-y i, Chin J Nosocomiol Vol.19 No.4	OBJECTIVE To analyze the effect of the disposable over-shoes for the control of no social infection of the intensive ca re units (ICU). METHODS The effects of the disposable over-shoe s for the environment contamination and no so comical infection control of the surgical ICU were investigated. RESULTS The mean of air bacteria colony counts when disposable over-shoe s were worn was lower than that when without their use by healthcare workers (P <0 .05);but their eligible rate of object surface bacteria counts up to health standard was no significant difference (P >0.05).The rates of no sociomoral infection be teen them w ere 21.5 ‰ and 17 .1 ‰, respectively .CONCLUSIONS The use of disposable

		2009	over-shoes can′ t improv e the environment quality and is not benefit for the control of nosocomial infection of surgical ICU.

5.2 Analysis of Post-Marketing Data

The Shoe Cover has been placed on the market for many years. We did not receive customer complains about product effectiveness and safety. The customer feedback of the propose device and similar device are shown in the table below.

Table5 Customer feedback list of the propose device

NO.	Description	Root Cause	Corrective actions	state
0	/	/	/	/

Table6 Post Market experience of similar device

Area	Time	Quantity	Complaints	Adverse events
China	2018	600,000,000.00	0	0
	2019	700,000,000.00	0	0
	2020	1,000,000,000.00	0	0
EU	2018	10,000,000.00	0	0
	2019	20,000,000.00	0	0
	2020	50,000,000.00	0	0
USA	2018	200,000,000.00	0	0
	2019	400,000,000.00	0	0
	2020	600,000,000.00	0	0
Total	3,580,000,000.00			

The Shoe Cover manufactured by Hubei Zhencheng Nonwoven Products Co., Ltd. intended to be used in hospital, clinic, beauty salon, food production industry, building, purification workshop or clean room, outdoors to keep from external harmful material. The similar device has been sold to many countries for many years and the use of Shoe Cover is mature. The manufacture has established quality management system and strictly follow the work instructions to ensure the product quality. The PMS data including customer feedback, customer complain are continuously collect to monitor the safety and effectiveness of Shoe Cover.

Literature, the safety tests, biocompatibility tests and General Safety and Performance Requirement demonstrate that the propose device is safe and effectiveness. The risk about propose device has been identified and mitigated to be acceptable or as low as reasonable practice.

Base on the evaluation of clinical literature, PMS data of the propose device, PMS data of similar device, General Safety and Performance Requirement, risk analysis of

propose device. The overall clinical risk of the propose device Shoe Cover is low and acceptable. This clinical evaluation is complied with MDR (EU) 2017/745.

6.Next Clinical Evaluation

As extensively outlined above, the use of Shoe Cover is well-established and the safety profile is well-known without significant risks. Safety and performance of this product has been examined and documented in many clinical studies. Moreover, extensive experience in clinical practice and post-marketing data support the performance and safety profile of Shoe Cover in the claimed indications.
The clinical evaluation will be updated once per three years normally, but should be updated immediately if significant risk were found.

7. Declaration of interests

Sun Jinfeng, Tina Cui, Raymond Luo, are hired by Hubei Zhencheng Nonwoven Products Co., Ltd. as clinical evaluator of Shoe Cover from 25/01/2021 to 26/03/2021 to participate in the clinical evaluation. In order to ensure the validity and impartiality of clinical evaluation. We make a declaration of interests as follow.

- The clinical evaluation does not involve any financial interests of ourselves;
- The clinical evaluation does not involve any financial interests of our family members;
- The clinical evaluation does not involve any ownership/ shareholding possibly affected by the outcome of the evaluation;
- The clinical evaluation does not involve any grants sponsored by the manufacturer;
- The clinical evaluation does not involve any benefits such as travelling or hospitality;
- The clinical evaluation does not involve any interests in connection with intellectual property, such as patents, copyrights and royalties possibly affected by the outcome of the evaluation.

NAME *SIGNATURE* *DATE* ***25/01/2021***

8. Reference

[1] Justin Galvin BSc a, Ahmad Almatroudi MPH a, Karen Vickery PhD a, Anand Deva MBBS a, Lillian Kelly Oliveira Lopes MN a,b, Dayane de Melo Costa MN a,b, Honghua Hu PhD. Patient Shoe Covers: Transferring bacteria from the floor on to surgical bedsheets, American Journal of Infection Control (2016)

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Biological Evaluation Report

File No.: CE/MDR-HBZC-03-06

Version: A/0

Product: Shoe Cover

Issued By	Reviewed By	Approved By	Effective Date
Zhang Yueqiong	Tang Meirong	Ceng Xinquan	2021.02.25

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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Zhang Yueqiong	2021.02.25

1. Foreword

This report is to describe the biological risk control carried on the Shoe Cover manufactured by our company. All potential biological 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.

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 by taking proper measures.

2. Purpose

Aim of this risk control is to carry out determination on the biological risks that may be led by the Shoe Cover 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.

3. Documents reference

EN ISO14971:2019, Medical devices - Application of risk management to medical devices

ISO10993-1:2018 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process

4. Categorization of medical devices

4.1 Categorization by nature of body contact

Surface-contacting devices

These include medical devices in contact with the following.

Non-woven

The physical and chemical property of non-woven is shown as below.

Material	Physical property	Chemical property
Shoe Cover	The non-woven fabric is made of polypropylene spun directly into a mesh and thermally bonded. The strength of the product is better than that of the general short-fiber product.	Antibacterial and anti-chemical agents. Polypropylene is a chemically passive substance, not moth-eaten, and can isolate the erosion of bacteria and insects in the liquid; antibacterial, alkali corrosion, and finished products do not affect the strength due to erosion

4.2 Categorization by duration of contact

Medical devices shall be categorized according to the anticipated duration of contact as follows.

a) Limited exposure (A) – devices whose cumulative single, multiple or repeated use or contact is up to 24 h.

The framework for the development of an assessment programme is as below:

Table 1 — Evaluation tests for consideration

Table A.1 — Endpoints to be addressed in a biological risk assessment

Medical device categorization by			Endpoints of biological evaluation														
Nature of body contact		Contact duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (>30 d)	Physical and/or chemical information	Cytotoxicity		Irritation or intracutaneous reactivity	Material mediated pyrogenicity[a]	Acute systemic toxicity[b]	Subacute toxicity[b]	Subchronic toxicity[b]	Chronic toxicity[b]	Implantation effects[b,c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive/ developmental toxicity[d,e]	Degradation[f]
Surface medical device	Intact skin	A	X[g]	E[h]	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal membrane	A	X	E	E	E											
		B	X	E	E	E		E	E			E					
		C	X	E	E	E		E	E	E	E	E		E			
	Breached or compromised surface	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		
Externally communicating medical device	Blood path, indirect	A	X	E	E	E	E	E					E				
		B	X	E	E	E	E	E	E				E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue/ bone/ dentin[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Circulating blood	A	X	E	E	E	E	E					E	E[j]			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

Table A.1 *(continued)*

Medical device categorization by			Endpoints of biological evaluation														
Nature of body contact		Contact duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (>30 d)	Physical and/or chemical information	Cytotoxicity		Irritation or intracutaneous reactivity	Material mediated pyrogenicity[a]	Acute systemic toxicity[b]	Subacute toxicity[b]	Subchronic toxicity[b]	Chronic toxicity[b]	Implantation effects[b,c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive/developmental toxicity[d,e]	Degradation[f]
Implant medical device	Tissue/bone[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

[a] Refer to ISO 10993-11:2017, Annex F.

[b] Information obtained from comprehensive implantation assessments that include acute systemic toxicity, subacute toxicity, subchronic toxicity and/or chronic toxicity may be appropriate if sufficient animals and timepoints are included and assessed. It is not always necessary to perform separate studies for acute, subacute, subchronic, and chronic toxicity.

[c] Relevant implantation sites should be considered. For instance medical devices in contact with intact mucosal membranes should ideally be studied/ considered in contact with intact mucosal membranes.

[d] If the medical device can contain substances known to be carcinogenic, mutagenic and/or toxic to reproduction, this should be considered in the risk assessment.

[e] Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, medical devices with relevant target populations (e.g. pregnant women), and/or medical devices where there is the potential for local presence of device materials in the reproductive organs.

[f] Degradation information should be provided for any medical devices, medical device components or materials remaining within the patient, that have the potential for degradation.

[g] X means prerequisite information needed for a risk assessment.

[h] E means endpoints to be evaluated in the risk assessment (either through the use of existing data, additional endpoint-specific testing, or a rationale for why assessment of the endpoint does not require an additional data set). If a medical device is manufactured from novel materials, not previously used in medical device applications, and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered. For particular medical devices, there is a possibility that it will be appropriate to include additional or fewer endpoints than indicated.

[i] Tissue includes tissue fluids and subcutaneous spaces. For gas pathway devices or components with only indirect tissue contact, see device specific standards for biocompatibility information relevant to these medical devices.

[j] For all medical devices used in extracorporeal circuits.

4.3 Biological safety assessment

According to ISO10993-1:2018, The assess route is performing Cytotoxicity, Sensitization, Irritation (including intracutaneous reactivity) test and completing risk management.

Besides, according to ISO10993-1:2018 Annex A.1 Endpoints to be addressed in a biological risk assessment, non-woven is intended to contact with the intact skin of human body, the contact time is less than 24H. Cytotoxicity, Sensitization, Irritation (including intracutaneous reactivity) were performed on the product. In Vitro Cytotoxicity Test Using ISO10993-5:2009 Test Method MTT Method MEM with 10% FBS extract, Skin Sensitization Test Using ISO10993-10:2010 Test Methods Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract, Intracutaneous Reactivity Test using ISO 10993-10:2010 Test Method 0.9% Sodium Chloride Injection Extract were performed, all the tests results showed the product possess a good biocompatibility properties.

5. Testing and test reports

Biocompatibility Evaluation Report

Item	Standard	Test Item	Test report
1	ISO10993-5:2009 Biological	Cytotoxicity test	SDWH-M202000537-1

	evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity		
2	ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Skin sensitization test	SDWH-M202000537-2
3		Skin irritation test	SDWH-M202000537-3

6. Conclusion

According to ISO14971 and ISO 10993-1 requirements, we have completed the biological evaluation for the Shoe Cover, the available information is sufficient to meet the purpose of the evaluation of biological safety, the Shoe Cover biological risks are acceptable, needn't further control measures.

Annex1: biological evaluation process

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

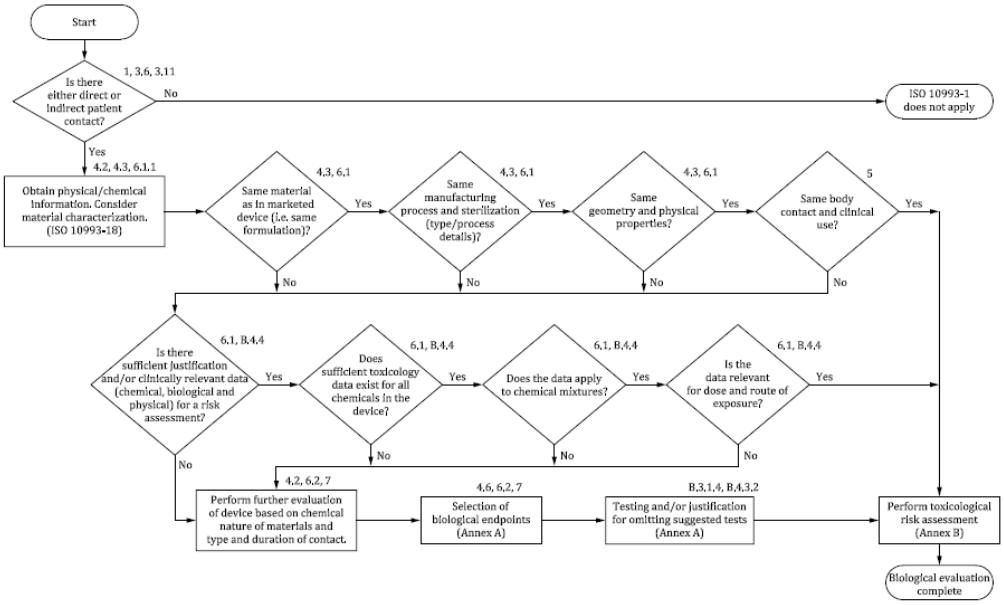

Figure 1 — Summary of the systematic approach to a biological evaluation of medical devices as part of a risk management process

Label

File No.: CE/MDR-HBZC-03-07

Version: A/0

Product: Shoe Cover

Issued By	Reviewed By	Approved By	Effective Date
Zhang Yueqiong	Tang Meirong	Ceng Xinquan	2021.02.25

Hubei Zhencheng Nonwoven Products Co., Ltd.
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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Zhang Yueqiong	2021.02.25

Label Sample

Shoe Cover CE MD

MODEL: Non woven shoe cover, PE/CPE shoe cover

YYYY-MM-DD LOT YYYYMMDD YYYYMMDD

NON STERILE

1. The packaging is intact
2. Only for single use.

UDI

Company: Hubei Zhencheng Nonwoven Products Co., Ltd.
Address:Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China
Email: jasmine@hbzhencheng.com

EC REP

Company: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Doc No.: CE/MDR-HBZC-03-07 Rev: A/0 Issue Date: 2021.02.25

Instructions for Use

CE

Name: Shoe Cover
Model: Non woven shoe cover, PE/CPE shoe cover
Intend Use: The product provides general protection. It can be used as general isolation in clinic, ward or laboratory. It is not intended to use in operation room.

Caution:
1.This product is for one-time use only.
2.It shall be properly treated as required and followed the local laws and regulations after use.
3.Never share your product with others.
4.Wash your hands thoroughly upon removal of the product.
5.Use with caution when you are allergic to nonwoven fabrics.

Warning:
1. Once the Shoe Covers get dirty and cannot provide further protection, please change another new one.
2. Only for single use.

Instruction for use:
Wear on feet or shoes directly.

Storage：
The product should be stored in a cool, dry, well ventlated and clean environment. Keep away from direct sunlight and heat source.

Shelf life: 2 years

【Expired Date】 MM/DD/YYYY

【Batch No.】 D/******

Labels, Packing Logo Design:

Symbol	Introductions	Symbol	Introductions
LOT	Batch Code		Do not reuse" are "single use, "Use only once
	Warnings and Precautions		non-sterile

MD	medical device		Manufacture Date
	Manufacturer Name Address	EC REP	Name and Address of European Union Representative
	Keep away from sunlight		Keep dry
	Use-by date		Consult instructions for use
	Do not use if package is damaged	CE	CE Symbol

Manufacturer Information

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European Authorized Representative

EC REP

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