CE Technical Files

Alcohol swab

File No.: CE/MDR-AS-01

Version: A/1

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Issued By	DAWEI ZHANG	Date	2021.9.9
Reviewed By	HONGFENG SHAO	Date	2021.9.9
Approved By	LILY	Date	2021.9.9

Manufacturer:
Yangzhou Super Union Import & Export Co., Ltd.

Address:
No.120 Xishan South Road Chenji Town 211408 Yizheng City,Yangzhou City,Jiangsu Province CHINA

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial Release	DAWEI ZHANG	2021.7.9
A/1	Added Basic UDI-DI and SRN	DAWEI ZHANG	2021.9.9

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1 General Description

1.1 Device description and specification

The Alcohol swab is pre-soaked with Medicinal alcohol and intended to inhibit the growth of microorganisms on the skin. It is typically used in medical device cleaning and for skin cleaning prior to injection. This is a single use, disposable device(s), provided non-sterile.

The product picture and specification of Alcohol swab are shown as below.

Product Name	Alcohol swab
Model/Specifications	3*6CM,3*6.5CM,5*5CM,As per customer requirements
Picture	
Material	Non-woven fabric,Isopropanol,water

Intend Use:
This product is used in medical device cleaning and for skin cleaning prior to injection. This is a single use, disposable device(s), provided non-sterile.

Package
100pcs/box,100boxes/ctn
We pack the quantity and pack system style under the customer’s requirements or the product specifications.

Cautions:
1. Avoid using if package in damaged.
2. Avoid contact with eyes, if contacted, flush eyes with copious amounts of water.
3. In the event of skin irritation or rash, discontinue use.
4. Store in a cool dry place, keep out of children.
5. Waste disposal according to related regulations.

Instruction for use

Tear open the package and ready for use

Storage

Avoid high temperature, moisture.

Disposal

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

Shelf Life

Five years.

Applicable Standard

Table 2. Applicable Standard

No.	File No.	File Title
1	Regulation (EU) 2017/745	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	EN 1041:2008+A1:2013	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
5	ISO 10993-1:2018	Biological evaluation of medical devices---part 1: Evaluation and testing
6	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
7	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Classification

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

Basic UDI-DI

6974265590001746

SRN

CN-MF-000010954

1.2 Reference to previous and similar generations of the device

The Alcohol swab is used in medical device cleaning and for skin cleaning prior to injection. This is a single use, disposable device(s), provided non-sterile. When we developed the Alcohol swab, similar products were already widely sold and used in the market, so no previous and similar generations of devices existed.

2 Information to be supplied by the manufacturer

2.1 Label and Language

The label was designed according to the standard of EN ISO 15223-1：2016 and requirement of Clause 23.2, Annex I <General Safety and Performance Requirements> of Regulation (EU) 2017/745.

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 Symbols used for device

Symbol	Explain
CE	After passing CE certification, mark of CE needs to be printed on labels; a) Diameter of the pattern shall not be less than 5mm. b) CE marking shall be distinct, visible durable and in clear writing.
EC REP	Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY" This symbol shall be accompanied by the name and the address of the authorised representative in the European Community, adjacent to the symbol (see A.8). 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.
	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.
	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.

	Symbol for “Use-by date”. Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown.
	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".
	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”.
	Symbol for “Medical device”
	Symbol for “Non sterile product” Indicates a medical device that has not been subjected to a sterilization process. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.
	Symbol for "Keep dry" Indicates a medical device that needs to be protected from moisture. NOTE This symbol can also mean “Keep away from rain” as referenced in ISO 7000.
	Symbol for “Keep away from Sunlight”. Indicates a medical device that needs protection from light sources.
	Symbol for “Consult instructions for use” Indicates the need for the user to consult the instructions for use. NOTE 1 Synonym for “Consult instructions for use” is “Consult operating instructions”. NOTE 2 Consider the difference between the description of this symbol and that of symbol for “Caution”.

	Symbol for "Do not use if package is damaged" NOTE This symbol may also mean “Do not use if the product sterile barrier system or its packaging is compromised”.
	Symbol for "DO NOT RE-USE" NOTE Synonyms for “Do not reuse” are “single use” and “use only once”.
	Symbol for “Humidity limitation” Indicates the range of humidity to which the medical device can be safely exposed.
	Symbol for “Temperature limit”

2.1.3 Examples of symbols application

A.1 Example of use of symbol for "BATCH CODE"

A.2 Examples of use of symbol for "DATE OF MANUFACTURE"

2004-06

A.3 Examples of use of symbol for "CATALOGUE NUMBER"

REF ABC123

A.4 Example of use of symbol for "MANUFACTURER"

Company Name:
Company
Address:

A.5 Example of use of symbol for “MANUFACTURER” combined with “DATE OFMANUFACTURE”

Company Name:
Company Address:
Manufacture Date:

A.6 Example of use of symbol for " AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

EC Rep Name:
EC Rep Address:

2.1.4 Language Requirements for Labeling in the EU Member States

Language / Country	Bulgarian	Croatian	English	Czech	Dutch	Danish	Estonian	Finnish	French	German	Greek	Hungarian	Irish	Italian	Latvian	Lithuanian	Maltese	Polish	Portuguese	Romanian	Slovak	Slovenian	Spanish	Swedish	Norwegian
Austria										★															
Belgium					★				★																
Bulgaria	★																								
Cyprus											★														
Croatia		★																							
Czechia				★																					
Denmark						★																			
Estonia							★																		
Finland								★																	
France									★																
Germany										★															
Greece											★														
Hungary												★													
Ireland			★										★												
Italy														★											
Latvia															★										
Lithuania																★									
Luxembourg									★	★															
Malta			★														★								

Netherlands					★																				
Poland																		★							
Portugal																			★						
Romania																				★					
Slovakia																					★				
Slovenia																						★			
Spain																							★		
Sweden																								★	
Norway																									★
Switzerland									★	★															
Iceland			★																						

Label Sample

Alcohol swab CE MD

Model:


YYYY-MM-DD

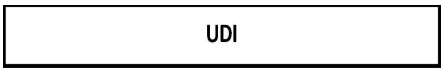
YYYYMMDD


YYYYMMDD

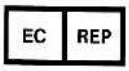








Yangzhou Super Union Import & Export Co., Ltd.
No.120 Xishan South Road Chenji Town 211408 Yizheng City,
Yangzhou City,Jiangsu Province CHINA
Tel: +86 0514-80783529 Fax:+86 0514-80783529
Website: https://sumed.en.alibaba.com/
E-mail: sales4@ysumed.com



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

Instructions for Use

CE

Name: Alcohol swab

Model:3*6CM,3*6.5CM,5*5CM,As per customer requirements

Intended Use

This product is used in medical device cleaning and for skin cleaning prior to injection. This is a single use, disposable device(s), provided non-sterile.

Cautions

1.Avoid using if package in damaged.
2.Avoid contact with eyes, if contacted, flush eyes with copious amounts of water.
3.In the event of skin irritation or rash, discontinue use.
4.Store in a cool dry place, keep out of children.
5.Waste disposal according to related regulations.

Main material:

Washing(water-repellent)nonwoven fabrics, Isopropyl alcohol, aluminium-foil mill and so on

Instruction for use:

Tear open the package and ready for use

Packaging and Storage:

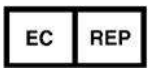
Avoid high temperature, moisture.

Shelf Life

Five years

Labels, Packing Logo Design:

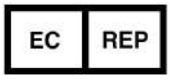
Symbol	Introductions	Symbol	Introductions
	Batch Code		Do not reuse" are "single use, "Use only once
	Don’t use when packing damaged		non-sterile

	Warnings and Precautions		Manufacture Date
	medical device		Consult instructions for use
	Use until year & month (Expiration date)		Keep dry
	Keep away from sunlight		Name and Address of European Union Representative
	Manufacturer Name Address		CE Symbol

Manufacturer Information

Yangzhou Super Union Import & Export Co., Ltd.
No.120 Xishan South Road Chenji Town 211408 Yizheng Ci
ty,Yangzhou City,Jiangsu Province CHINA
Tel: +86 0514-80783529 Fax:+86 0514-80783529
Website: https://sumed.en.alibaba.com/
E-mail: sales4@ysumed.com

European Authorized Representative



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

3 Design and Manufacturing Information

The design and manufacturing activities are performed by our company Yangzhou Super Union Import & Export Co., Ltd.

Company: Yangzhou Super Union Import & Export Co., Ltd.

Address:

No.120 Xishan South Road Chenji Town 211408 Yizheng City,Yangzhou City,Jiangsu Province CHINA

Company Introduction

Yangzhou Super Union Import & Export Co., Ltd was founded in 2012 year.We are a professional supplier of medical products.We have own factory secialized in manufacturing Gauze ball, Lap sponge, Gauze swab, Gauze bandage, Gauze roll, Self Adhesive Bandage, Non Woven Swab, Combine Pad, Wound Dressing Roll, Zinc Oxide Plaster, Silk tape, Non woven tape, Bouffant cap, Clip cap, PBT bandage, Triangular bandage, Alcohol swab, CPR mask,Kinesiology tape ,Coverall,Cotton roll ,Under pad,Breathing exerciser and other medical products.

We can also manufacture as per customer requirements and provide OEM and ODM service.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 054843 0021 Rev. 02

Holder of Certificate: **Yangzhou Super Union Medical Material Co., Ltd.**
No.118 Xishan South Road, Chenji Town
211408 Yizheng
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

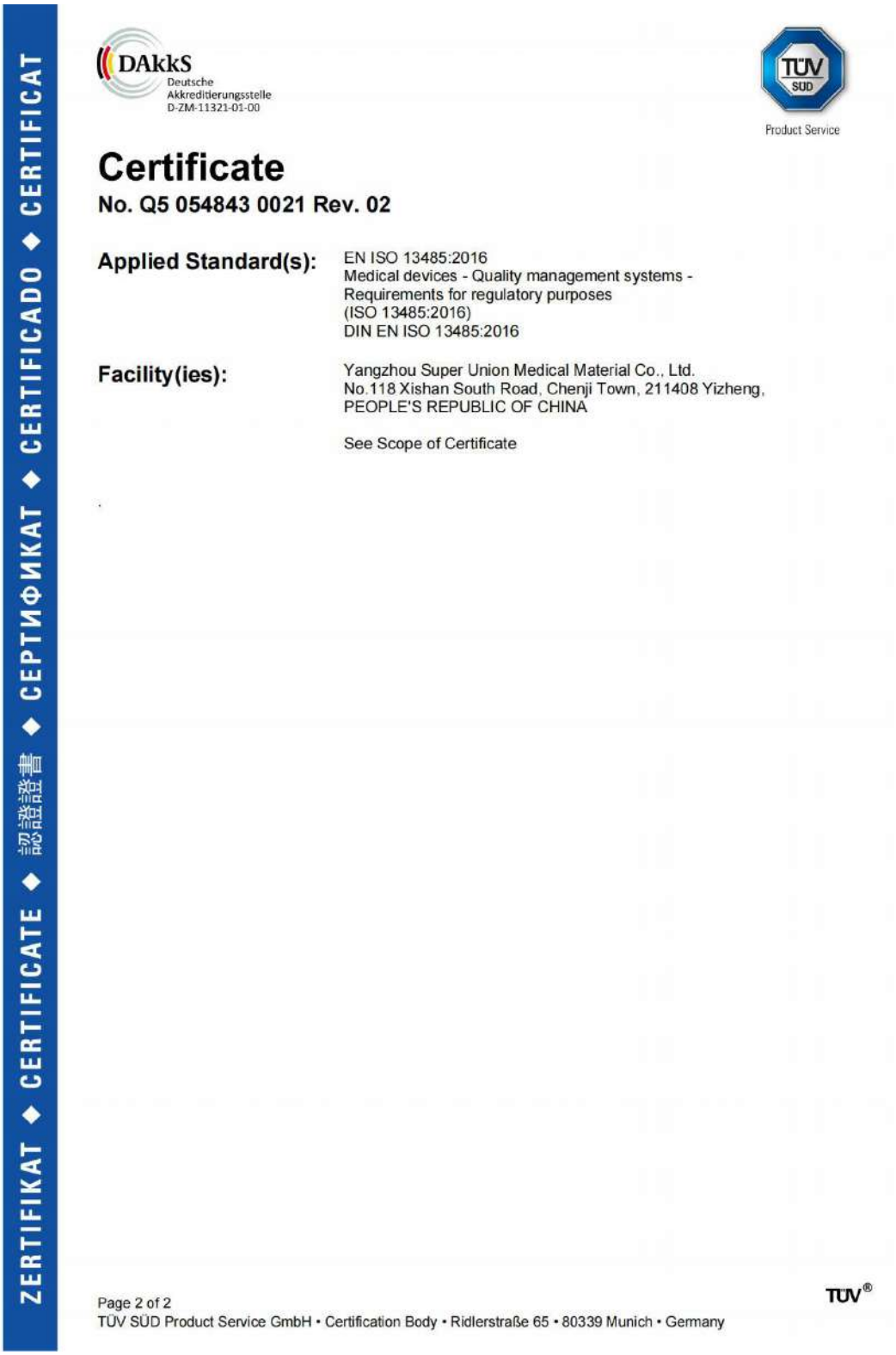
Scope of Certificate: **Design and Development, Production and Distribution of Sterile Paraffin Gauze Dressing
Production and Distribution of Sterile Gauze Swabs with X-ray Detectable Material, Sterile Gauze Swabs without X-ray Detectable Material, Sterile Lap Sponges with X-ray Detectable Material, Sterile Lap Sponges without X-ray Detectable Material, Sterile Non-woven Sponges with X-ray Detectable Material, Sterile Non-woven Sponges without X-ray Detectable Material, Sterile Gauze Bandages, Sterile Non-woven Rolls,Cotton Wool Roll,Cutting Gauze,Sterile Gauze Cut, Sterile Gauze Cut with X-Ray Detectable Material, Sterile Gauze Ball with X-Ray Detectable Material, Sterile Gauze Ball, Gauze Roll, Sterile Non Woven Ball with X-Ray Detectable Material, Sterile Non Woven Ball, Gauze Roll with X-Ray
Detectable Material, Sterile Non Woven Cut with X-Ray Detectable Material, Sterile Non Woven Cut, Sterile Non Woven Bandages, Sterile Non Woven Roll, Sterile Gauze Tampons, Sterile Gauze Tampons With X-Ray Detectable Material, Medical Face Mask**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 054843 0021 Rev. 02

Report No.: SH2004501
Valid from: 2021-06-15
Valid until: 2023-04-30

Date, 2021-06-15

Christoph Dicks
Head of Certification/Notified Body



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 054843 0021 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Yangzhou Super Union Medical Material Co., Ltd.
No.118 Xishan South Road, Chenji Town, 211408 Yizheng,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Page 2 of 2
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Figure1 ISO13485:2016 Certificate

Manufacturing Information

We manufacture the Alcohol swab by strictly following the Quality Control Procedure, and the manufacturing process is shown as below:

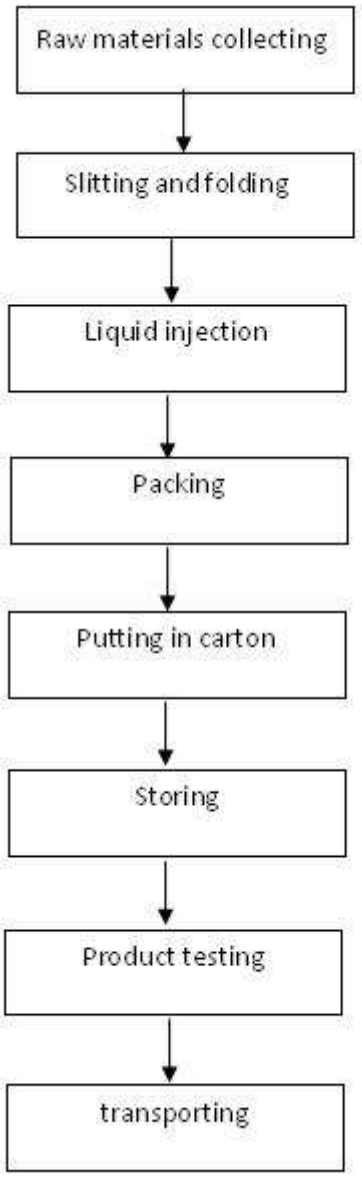


Figure2 manufacturing process

The special process is Liquid injection., the key process is Product testing.

General Safety and Performance Requirements

File No.: CE/MDR-AS-01-04

Version: A/1

Product: GMDN 13913

Antiseptic swab

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 Risk Management Report CE/MDR-AS-01-05 Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2
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-AS-01-05
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;	A	ENISO14971：2019	Risk Management Report: CE/MDR-AS-01-05

	(b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.			
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-AS-01-05
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	A	ENISO14971：2019	Risk Management Report

	and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).			CE/MDR-AS-01-05
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 Risk Management Report CE/MDR-AS-01-05 Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2
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-AS-01-05
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	A	ENISO14971：2019	Risk Management Report CE/MDR-AS-01-05

	normal conditions of use.			
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	A	ENISO15223-1:2016 EN1041:2008+A1:2013 ISO10993-1：2018 ENISO10993-5:2009 ENISO10993-10:2013	Label & IFU Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2

	(h) the confirmation that the device meets any defined chemical and/or physical specifications.			
	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	Lable & IFU
	10.3. Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.	NA		
	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	A	ENISO14971：2019	Risk Management Report CE/MDR-AS-01-05

	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 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	NA		The device does not contain CMR or endocrine-disrupting substances

	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.			
	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, the guidelines shall be updated.	NA		The device does not include phthalates.
	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		The device does not contain other CMR or endocrine-disrupting substances
	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	A	ENISO15223-1:2016 EN1041:2008+A1:2013	Lable & IFU CE/MDR-AS-01-02

	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.			
	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-AS-01-05
	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-AS-01-05
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, 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.	A	ENISO14971：2019	Risk Management Report CE/MDR-AS-01-05
	11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	A	ENISO15223-1:2016	Label & IFU CE/MDR-AS-01-02

			EN1041:2008+A1:2013	
	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		The device is not labelled as having a specific microbial state
	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		The device is not delivered in a sterile state.
	11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	NA		The device is not sterile.
	11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	NA		The device is not intended to be sterile.
	11.7. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	NA		The device is not needed to be sterilized before use.
	11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.	NA		The device is not sterile.
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	NA		

	absorbed by or locally dispersed in the human body.			
	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; (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	NA		The device does not contain materials of biological origin

	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		The device does not contain materials of biological origin
	13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients,	NA		The device does not contain materials of biological origin

	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		Construction of devices and interaction with their environment
	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		The device is not intended for use in combination with other devices or equipment
	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;	NA		The design and manufacture of device would not produce these risks.

	(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; (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		There is no risk of fire or explosion during normal use of the device.
	14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	NA		The device does not need adjustment, calibration or maintenance.
	14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	NA		The device is not intended to be operated together with other devices or products.
	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		It’s not measurement, monitoring or display scale device.

	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		The device is manufactured with normal safety material that can be safely disposed.
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		The device does not have diagnostic function.
	15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC	NA		The device does not have measuring function.
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		The device would not exposure of patients, users and other persons to radiation

	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		The device would not exposure of patients, users and other persons to radiation
	16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.	NA		The device would not exposure of patients, users and other persons to radiation
	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	NA		The device would not exposure of patients, users and other persons to radiation

	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.			
17	17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves	NA		This device does not incorporate electronic programmable systems
	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		This device does not incorporate electronic programmable systems
	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		This device does not incorporate electronic programmable systems
	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		This device does not incorporate electronic programmable systems
	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		This device does not incorporate electronic programmable systems

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		The device is not active devices
	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		The device is not active devices
	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		The device is not active devices
	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		The device is not active devices
	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		The device is not active devices
	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		The device is not active devices
	18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.	NA		The device is not active devices

	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		The device is not active devices
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		The device is not active implantable devices
	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		The device is not active implantable devices
	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		The device is not active implantable devices
	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	NA		The device is not active implantable devices

	device and its year of 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		The device will not pose mechanical or thermal risk to patient
	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		The device will not pose mechanical or thermal risk to patient
	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		The device will not pose mechanical or thermal risk to patient
	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		The device will not pose mechanical or thermal risk to patient
	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		The device will not pose mechanical or thermal risk to patient
	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		The device will not pose mechanical or thermal risk to patient
	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	NA		The device will not pose mechanical or

	dangerous temperatures under normal conditions of use.			thermal risk to patient
21	21. Protection against the risks posed to the patient or user by devices supplying energy or substances	NA		
	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		The device does not supply energy or substances to patient
	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		The device does not supply energy or substances to patient
	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		The device does not supply energy or substances to patient
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		The device is designed to be used by lay persons.
	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	NA		The device is designed to be used by lay persons.

	all stages of the procedure, if necessary after appropriate training and/or information, — reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and — reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.			
	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		The device is designed to be used by lay persons.
	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-AS-01-02
	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	ENISO15223-1:2016 EN1041:2008+A1:2013	label & IFU CE/MDR-AS-01-02 Printed label and IFU was used. a) Paper printed label is used. b) The information will

	(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. (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			be displayed on the packaging for each unit. c) Yes, human-readable format. d) Instructions for use will be provided together with devices. e) Not applicable. The device is provided in single packaging each piece. f) Electronic format instruction can be received from manufacturer. g) Limitations, contra-indications, precautions or warnings information will be provided by IFU or label if needed. h) Internationally

	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.			recognized symbols will be used.
	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; (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 the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;	A	ENISO15223-1:2016 EN1041:2008+A1:2013	label & IFU CE/MDR-AS-01-02 a) The device name is indicated. b) See [Intended Use] c) the manufacturer and the address information are indicated. d) The authorized representative and address of the registered place of business of the authorized representative are indicated; e) N/A f) N/A g) LOT NUMBER h) UDI-DI will be

	(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 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.			applied. i) Refer to IFU. j) Manufacture date was indicated on label. k) N/A. It's single used device. l) N/A m) N/A n) Symbol of single use is indicated. 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, (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.	NA		It's not sterile device.
	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.	A	ENISO15223-1:2016 EN1041:2008+A1:2013	label & IFU CE/MDR-AS-01-02 a) The points (a), (c) , (k),of Section 23.2 was indicated in IFU, the point (e), (f), (l), (n) and (r) of Section 23.2 is not

	(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 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			applicable to the device b) Intended use was indicated in IFU. c) N/A d) N/A e) See IFU Description of function f) N/A g) Warning and Caution information was described in IFU. h) N/A i) Pre-use check was described in IFU. j) N/A k) Usage method was provided in IFU. l) N/A

	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; (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			m) N/A n) N/A o) N/A p) Symbol of single use is indicated. q) N/A r) N/A

	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 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			s) See IFU [Contraindication].

	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: — 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;			t) N/A u) NA v) NA. w) The device is easy to operate. x) N/A y) Date of issue was indicated

	(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.			z) N/A aa) N/A ab) N/A

5 Risk Management Report

(According to EN ISO 14971: 2019)

File No.: CE/MDR-AS-01-05

Version: A/1

Product: GMDN 13913

Antiseptic swab

Chapter One Review

1. Product Introduction

Please refer to 01 TCF Section 1.1 Device description and specification.

1.1 Product Name

Alcohol swab

1.2 Product Function

Please refer to 01 TCF Section 1.1 Device description and specification.

1.3 Product Picture, Configuration and Material

Please refer to 01 TCF Section 1.1 Device description and specification.

1.4 Clinical background,current knowledges and state of art

Please refer to 05 Clinical evaluation report Section 3.Clinical background, current knowledge, state of the art.

2. Standard List

Regulations/Directive

- Medical Device Regulation: Regulation (EU) 2017/745

Guidance

- MEDDEV 2.7.1 revision 4 Clinical evaluation: A guide for manufacturers and notified bodies
- MEDDEV 2.12-1 rev 8 guidelines on a medical devices vigilance system
- MEDDEV 2.12-2 guidelines on post market clinical follow-up

Please refer to 01 TCF Section 1.1 Applicable Standard.

3. Risk Management Responsibilities and Authority Allocation

1) The general manager should provide the appropriate resources for the risk management, and take the responsibility for the risk management. Ensure that the allocation of personnel in charge of risk management, implementation and evaluation of the work are trained and qualified, and ensure that they have related knowledge and experience.

2) The technical department （R&D DP） is responsible for the product design and development process of risk management activities, the formation of risk analysis, risk assessment, risk control, comprehensive assessment of residual risk analysis and evaluation of the relevant records, and the preparation of risk management report.

3) The quality control department, sales department, production department and other relevant departments should analyze all the known and predictable hazards from the perspective of product realization, and the production and production of information collection and timely feedback to the technical department for risk assessment, if necessary, a new round of risk management activities.

4) The technical department（R&D DP）and the assessment team member shall review the results of the risk management activities regularly, and shall be responsible for the correctness and validity of the risk management activities.

5) The Document Control Center (DCC) is responsible for the collection of all risk management documents.

4. Risk Management Review Staff and Responsibilities

Note: please make corresponding increase or decrease according to the actual situation

Department	Assignment of responsibility
R&D Department	Responsible for the risk management implementation After production and production various stages collection of information and appraisal
R&D Department	Responsible for the risk management plan, the implementation, the risk appraisal and the confirmation and the establishment documents
Quality Department	From product examination and confirmation angle appraisal risk
Sales Department	From customer and service angle appraisal risk

5. Risk Management Plan(According to ISO/TR 24971:2020 clause 4.4)

1) **Plan the scope of risk management activities**

The risk management plan is mainly for the product in its entire life cycle (including design development, product realization, the final stop and disposal stage) for risk management activities of planning.

2) Formulation of responsibility and power–refer to the fifth section in Chapter one.

3) Assessment requirements for risk management activities I) whether the risk management plan has been properly implemented Review team members are responsible for the implementation of the risk management plan to verify, to view the risk management document to view the risk analysis, risk assessment, risk control and other records, to ensure that the risk management plan of risk management activities have been properly implemented. Verification of the effectiveness of risk management activities for II The evaluation group can be used to verify the effectiveness of the risk management activities by collecting clinical data and information on the production and production of the risk management.

4) The acceptable criteria for risk acceptability are determined by the manufacturer to determine the acceptable risk criteria for determining the risk acceptable to the first section of the second chapter.

5) Verification activities–refer to Technical file Verification and Validation Data.

6) Activities related to the collection and evaluation of information related to the production and production after production–Refer to Technical file Post Market Surveillance.

7) This risk management plan was established in accordance with EN ISO 14971 and considers the recommendations of all informative attachments of this standard.

This risk management plan is in accordance with all requirements listed in appendix F of EN ISO 14971. Its task is to describe the risk management process for the concerned product to identify potential risks, evaluate them and to control them effectively. This risk management plan describes the risk management process of the manufacturer for the above-mentioned medical device. It covers all phases of the life cycle, starting with the concept (design and development control), production, storage / despatch up to decommissioning or waste disposal in accordance with EN ISO 14971 Appendix F.1and F.2.

In this risk management plan the following areas are covered:

---Description of the medical device and designation of the performance properties

---Designation of personnel, responsibilities and competence within the risk management process

---Evaluation of the risk management process through the management

---Criteria for the acceptability of risks

---Flow chart of the risk management process

8) Personnel and Responsibilities in the Risk Management Process

The personnel and responsibilities in the risk management process was designated in chanpter4

9) Criteria to Analyze and Evaluate the Acceptability of Risk

Risk severity level

Table 1. Severity Level

Grading	Level	Risk System Definition
1	Negligible	Inconvenience or temporary discomfort
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
3	Serious	Results in injury or impairment requiring professional medical intervention
4	Critical	Results in permanent impairment or life-threatening injury
5	Catastrophic	Results in patient death

Risk Frequency Level

Risk management team shall analysis the hazard, on the perspective of loss probability and

severity, and record.

Table 2. Probability Level

Probability Grading	Level	Scope Definition
1	Improbable	$< 10^{-6}$
2	Remote	$< 10^{-5}$ and $\geq 10^{-6}$
3	Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
4	Probable	$< 10^{-3}$ and $\geq 10^{-4}$
5	Frequent	$\geq 10^{-3}$

Acceptance Criteria

	Qualitative severity levels				
Probability	**1 Negligible**	**2 Minor**	**3 Serious**	**4 Critical**	**5 Catastrophic**
P5. Frequent	NAC	NAC	NAC	NAC	NAC
P4. Probable	NAC	NAC	NAC	NAC	NAC
P3. Occasional	AC	NAC	NAC	NAC	NAC
P2. Remote	AC	AC	NAC	NAC	NAC
P1. Improbable	AC	AC	AC	NAC	NAC

NAC=unacceptable AC= Acceptable

The estimated risk to each hazard/ reason is written list with the form of classification (NAC/AC), give clear indication if it has control measures.

Identification of qualitative and quantitative characteristics(According to ISO/TR 24971:2020 Annex A)

Item	Questions	Answer / Comments
A.2.1	What is the intended use and how is the medical device to be used?	
A.2.2	Is the medical device intended to be implanted?	
A.2.3	Is the medical device intended to be in contact with the patient or other persons?	
A.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	
A.2.5	Is energy delivered to or extracted from the patient?	
A.2.6	Are substances delivered to or extracted	

	from the patient?	
A.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	
A.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	
A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	
A.2.10	Does the medical device modify the patient environment?	
A.2.11	Are measurements taken?	
A.2.12	Is the medical device interpretative?	
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	
A.2.14	Are there unwanted outputs of energy or substances?	
A.2.15	Is the medical device susceptible to environmental influences?	
A.2.16	Does the medical device influence the environment?	
A.2.17	Does the medical device require consumables or accessories?	
A.2.18	Is maintenance or calibration necessary?	
A.2.19	Does the medical device contain software?	
A.2.20	Does the medical device allow access to information?	
A.2.21	Does the medical device store data critical to patient care?	
A.2.22	Does the medical device have a restricted shelf-life?	
A.2.23	Are there any delayed or long-term use effects?	
A.2.24	To what mechanical forces will the medical device be subjected?	
A.2.25	What determines the lifetime of the medical device?	
A.2.26	Is the medical device intended for single use?	
A.2.27	Is safe decommissioning or disposal of the medical device necessary?	
A.2.28	Does installation or use of the medical device require special training or special skills?	
A.2.29	How will information for safety be provided?	
A.2.30	Are new manufacturing processes established or introduced?	
A.2.31	Is successful application of the medical	

	device critically dependent on the usability of the user interface?	
A.2.31.1	Can the user interface design features contribute to use error?	
A.2.31.2	Is the medical device used in an environment where distractions can cause use error?	
A.2.31.3	Does the medical device have connecting parts or accessories?	
A.2.31.4	Does the medical device have a control interface?	
A.2.31.5	Does the medical device display information?	
A.2.31.6	Is the medical device controlled by a menu?	
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge,skills and abilities?	
A.2.31.8	Will the medical device be used by persons with special needs?	
A.2.31.9	Can the user interface be used to initiate unauthorised actions?	
A.2.32	Does the medical device include an alarm system?	
A.2.33	In what way(s) might the medical device be misused(deliberately or not)?	
A.2.34	Is the medical device intended to be mobile or portable?	
A.2.35	Does the use of the medical device depend on essential performance?	
A.2.36	Does the medical device have a degree of autonomy?	
A.2.37	Does the medical device produce an output that is used as an input in determining clinical action?	

10) Controlling of the Management Process

The risk management will be achieved continuously, to analyze the experience achieved with the product in question, to evaluate the risk situation and to document this appropriately in the risk management worksheet. If necessary, or in case of special incidents, the management or its deputy will initiate an extraordinary meeting with responsible person. The management controls include the evaluation of actions taken as well as the success of these actions. It includes also the evaluation of available information about competitors' products.

11)Controlling of the risk analysis process

The flow chart describes the levels of realization of the management process and designates single steps for the risk analysis, risk evaluation, action management and the risk controlling.

The flow chart is seen **<Figure B.1 — Overview of risk management activities as applied to medical devices> of EN ISO14971:2019**.

Step 1: Intended Use and Identification of Characteristics Related to the Safety of the Medical Device(According to ISO/TR 24971:2020 clause 5.2)

The intended use and each reasonably imaginable and foreseeable misuse will be described in the risk management plan together with the product performance properties, which may influence the safety of the medical device. Then, the performance properties will be taken over into the risk management worksheet and the risks will be evaluated which occur if these performance properties are not achieved. For describing the features of the medical device and its environment in which it is used, Annex C of the current standard ISO/TR 24971:2020 is applied.

Step 2: Identification of Hazards(According to ISO/TR 24971:2020 clause 5.4)

All known and foreseeable failures / dysfunctions / hazards, which infringe the function and safety of the medical device, will be identified. For this the medical device will be analysed in its regular mode, failure mode, (also in case of reasonably foreseeable misuse). Moreover already earlier discovered hazards, incidents or situations will be considered.

Step 3: Estimation of the Risk(s) for Each Hazardous Situation(According to ISO/TR 24971:2020 clause 5.4)

For each defined or assumed hazard of Step 2 the implied risk will be assessed. The expected physical damage or severity of harm, and probability of occurrence.

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation will be considered and the resulting hazardous situation(s) will be recorded.

Step 4: Risk Evaluation(According to ISO/TR 24971:2020 clause 6)

After that each risk will be evaluated, whether it is acceptable or not and whether a risk reduction is required. The criteria to evaluate the acceptability are listed in the risk management plan.

Step 5 and 6: Adopt risk control measures(According to ISO/TR 24971:2020 clause 7.2)

For risks which are within the acceptable area no actions of risk control will be taken. Risks, which are outside this area, will be treated case by case. Any risk control measures have the goal to reach at least the “AC“ (Acceptable).

The effectiveness of the risk control measures taken will be evaluated/verified and recorded in the risk management worksheet.

Step 7: Residual Risk Evaluation(According to ISO/TR 24971:2020 clause 7.2)

The residual risks will be evaluated and documented in the risk management worksheet. In case a residual risk is not acceptable, Step 5 and step6 will be repeated.

Step 8: Risk / Benefit Analysis(According to ISO/TR 24971:2020 clause 7.4)

Not acceptable risks can be accepted in exceptional cases, if a particularly high benefit is to be expected for the patient, and alternative products or treatment measures with minor risks are not available.

Step 9: Risks Arising from Risk Control Measures(According to ISO/TR 24971:2020 clause 7.5)

In this step whether the actions of risk control and/or risk reduction would introduce new hazards or hazardous situations will be evaluated. In this case Step 3 has to be repeated.

Step 10:Completeness of Risk Control(According to ISO/TR 24971:2020 clause 7)

In this step, whether all relevant risks have been considered and whether the risk evaluation process is complete will be checked. In case the risk evaluation is acknowledged as complete.

Step 11: Evaluation of Overall Residual Risk Acceptability(According to ISO/TR 24971:2020 clause 8)

After the completion of all risk control measures, the whole residual risks as well as the acceptability of the residual risks will be evaluated. The evaluation of the residual risks will be performed analogically to the evaluation of the basic risks.

Step 12: Result of risk management(According to ISO/TR 24971: 2020 clause 9)

There will be a summarizing risk management report. It will summarize the risk analysis, risk evaluation and management of preventive respectively risk control measures. This risk management report will be set up and released at least once per year by the management or its deputy

Step13: Production and post-production information(According to ISO/TR 24971: 2020 clause 10)

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

This product has been sold for many years. Once the product occurs upgrade or instead by new design, will be collected on various types of risk, and once again to analyze, evaluate, control, update the content of risk management report.

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.

Review of risk management experience:

As above, related members reviewed the risk management.

- Market complaints or grievances

Please refer to file <CE/MDR-AS-01-07 - Post Market Surveillance> Section 7.2.

Related records:

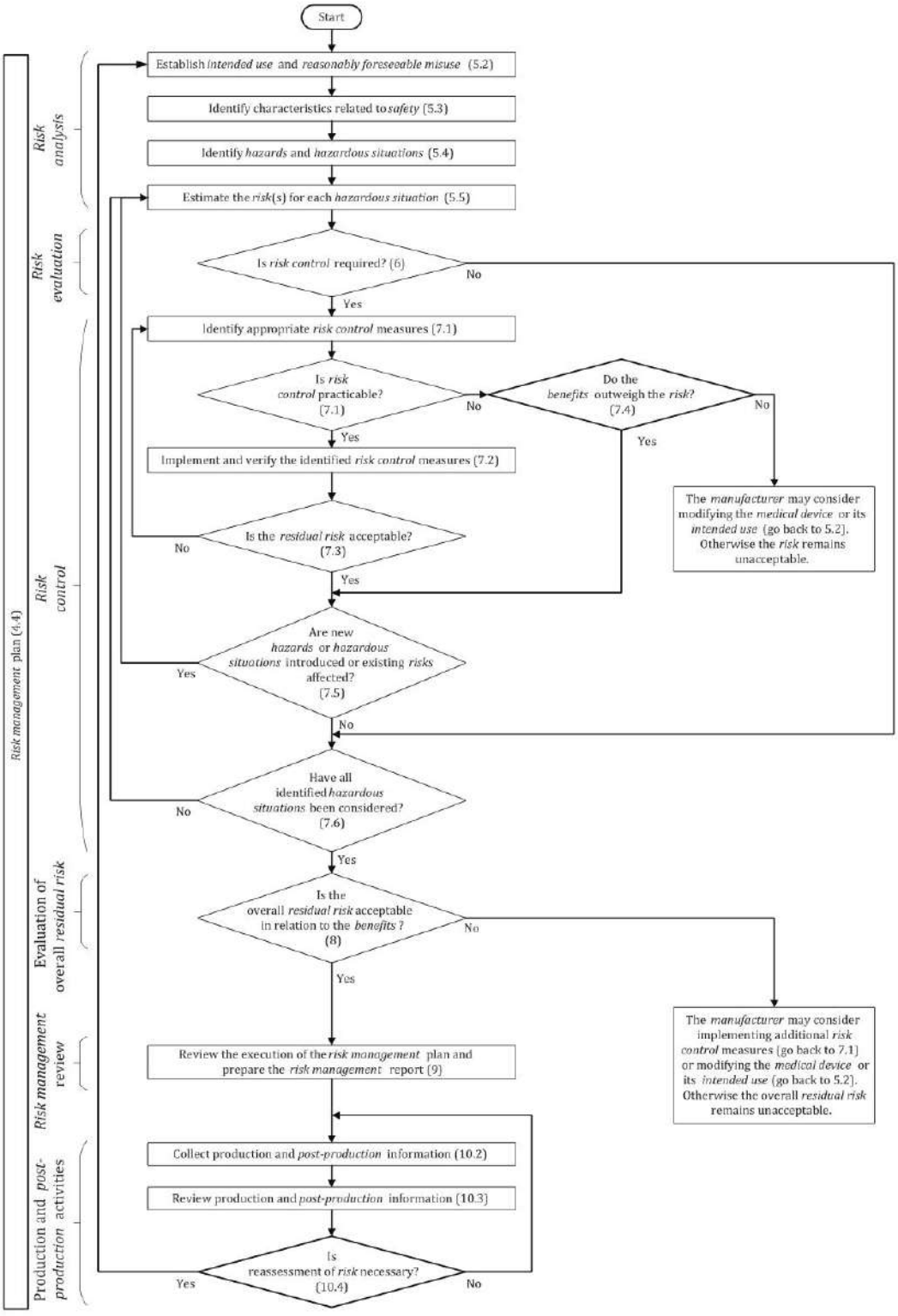
a) Customer feedback investigation (included in CER)

b) Sales information (included in CER)

c) Adverse event, recall, complaint, nonconformity (included in CER)

6. Risk Management Process

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



Chapter Two Risk Analysis

2.1 Risk evaluation criteria

2.1.1 Risk severity level

Table1 Severity Level

Grading	Level	Risk System Definition
1	Negligible	Inconvenience or temporary discomfort
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
3	Serious	Results in injury or impairment requiring professional medical intervention
4	Critical	Results in permanent impairment or life-threatening injury
5	Catastrophic	Results in patient death

2.1.2 Risk Frequency Level

Risk management team shall analysis the hazard, on the perspective of loss probability and severity, and record.

Table2 Probability Level

Probability Grading	Level	Scope Definition
1	Improbable	$< 10^{-6}$
2	Remote	$< 10^{-5}$ and $\geq 10^{-6}$
3	Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
4	Probable	$< 10^{-3}$ and $\geq 10^{-4}$
5	Frequent	$\geq 10^{-3}$

2.1.3 Acceptance Criteria

	Qualitative severity levels				
Probability	**1 Negligible**	**2 Minor**	**3 Serious**	**4 Critical**	**5 Catastrophic**
P5. Frequent	NAC	NAC	NAC	NAC	NAC
P4. Probable	NAC	NAC	NAC	NAC	NAC
P3. Occasional	AC	NAC	NAC	NAC	NAC
P2. Remote	AC	AC	NAC	NAC	NAC
P1. Improbable	AC	AC	AC	NAC	NAC

NAC=unacceptable AC= Acceptable

The estimated risk to each hazard/ reason is written list with the form of classification (NAC/AC), give clear indication if it has control measures.

Identification of qualitative and quantitative characteristics (According to ISO/TR 24971:2020 Annex A)

Item	Questions	Answer / Comments
A.2.1	What is the intended use and how is the medical device to be used?	Refer to IFU.
A.2.2	Is the medical device intended to be implanted?	NO.
A.2.3	Is the medical device intended to be in contact with the patient or other persons?	Yes, Contact with wearers skin. Biological hazards
A.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 material is non-woven fabric，which is intended to contact with user.
A.2.5	Is energy delivered to or extracted from the patient?	NO.
A.2.6	Are substances delivered to or extracted from the patient?	NO.
A.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO. single use
A.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO.
A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	NO. disposable
A.2.10	Does the medical device modify the patient environment?	NO.
A.2.11	Are measurements taken?	NO.
A.2.12	Is the medical device interpretative?	NO.
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO.
A.2.14	Are there unwanted outputs of energy or substances?	NO.
A.2.15	Is the medical device susceptible to environmental influences?	Refer to IFU.
A.2.16	Does the medical device influence the environment?	NO.
A.2.17	Does the medical device require consumables or accessories?	NO.
A.2.18	Is maintenance or calibration necessary?	NO.
A.2.19	Does the medical device contain software?	NO.
A.2.20	Does the medical device allow access to information?	NO.
A.2.21	Does the medical device store data critical to patient care?	NO.

A.2.22	Does the medical device have a restricted shelf-life?	YES. Refer to IFU.
A.2.23	Are there any delayed or long-term use effects?	Material performance, Biological hazards, information hazards, function hazards
A.2.24	To what mechanical forces will the medical device be subjected?	NO.
A.2.25	What determines the lifetime of the medical device?	Determined by the life time of material and storage environment
A.2.26	Is the medical device intended for single use?	Yes, information hazards
A.2.27	Is safe decommissioning or disposal of the medical device necessary?	NO.
A.2.28	Does installation or use of the medical device require special training or special skills?	NO.
A.2.29	How will information for safety be provided?	Yes, Instruction for Use. Information hazards ;operation hazards
A.2.30	Are new manufacturing processes established or introduced?	NO.
A.2.31	Is successful application of the medical device critically dependent on the usability of the user interface?	NO.
A.2.31.1	Can the user interface design features contribute to use error?	NO.
A.2.31.2	Is the medical device used in an environment where distractions can cause use error?	NO.
A.2.31.3	Does the medical device have connecting parts or accessories?	NO.
A.2.31.4	Does the medical device have a control interface?	NO.
A.2.31.5	Does the medical device display information?	NO.
A.2.31.6	Is the medical device controlled by a menu?	NO.
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge,skills and abilities?	NO.
A.2.31.8	Will the medical device be used by persons with special needs?	NO.
A.2.31.9	Can the user interface be used to initiate unauthorised actions?	NO.
A.2.32	Does the medical device include an alarm system?	NO.
A.2.33	In what way(s) might the medical device be misused(deliberately or not)?	NO.
A.2.34	Is the medical device intended to be mobile or portable?	YES.
A.2.35	Does the use of the medical device depend on essential performance?	The device is easy to operate.

A.2.36	Does the medical device have a degree of autonomy?	NO.
A.2.37	Does the medical device produce an output that is used as an input in determining clinical action?	NO.

Form 1.Risk Analysis, Control measurements and risk Evaluation after taking measures)

(According to ISO/TR 24971:2020 Annex C, ISO/TR 24971:2020 clause 7.4,7.5,7.6)

No.	Hazard		Risk Evaluation			RRM Risk Reduction Measure	Evidence	Risk Evaluation			NH	RL
	General	Identify hazards	S	P	RL			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	N/A										

	patient												
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 device is damaged or re-use the product.	3	3	NA C	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. 2.Ensure product quality by strictly follow the QMS	1.Instruction for use: CE/MDR-AS-01-02 2. Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2	3	1	AC	No	AC
2	Viruses	A, Patient may have a bacterial infection if did not use the product properly or re-use the product.	3	3	NA C	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. 2.Ensure product	1.Instruction for use: CE/MDR-AS-01-02 2. Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2	3	1	AC	No	AC

						quality by strictly follow the QMS						
3	Other agents (e.g. prions)	N/A										
4	Re- or cross-infection	Patient may got infection if	3	3	NAC	Indicate to users in the instruction manual do not	Instruction for use: CE/MDR-AS-01-02	3	2	AC	No	AC
5	Acids or alkalis	N/A										
6	Residues	N/A										
7	Contaminates	The products maybe contaminated if the package of device is damaged.	3	3	NAC	Indicate to users in the instruction manual how to use the product and indicate the user not to use the product if the package damaged.	Instruction for use: CE/MDR-AS-01-02	3	2	AC	No	AC
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	N/A										
14	Bio-incompatibility	A, The product may cause the user uncomfortable if the material is not meet the safety requirements.	3	3	NAC	1.Choose raw materials meeting the requirements; 2.Ensure the product possess good biocompatibility.	1. Incoming inspection report 2. Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2	3	1	AC	No	AC
15	Allergenicity	A, The product contact with patient and lead to allergenicity	3	3	NAC	1.Choose raw materials meeting the requirements; 2. Ensure the product possess good biocompatibility.	1. Incoming inspection report 2. Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2	3	1	AC	No	AC
16	irritancy	A, The product contact with patient and lead to irritancy	3	3	NAC	1.Choose raw materials meeting the requirements; 2. Ensure the product possess good biocompatibility.	1. Incoming inspection report 2 Biocompatibility Compliance Evidence CE/MDR-AS-01-06.2	3	1	AC	No	AC
17	Pyrogenicity	A, The product may	3	3	NAC	Choose raw materials meeting the	Biocompatibility Compliance	3	1	AC	No	AC

		cause the user uncomfortable is not meet the safety requirements.				requirements	Evidence CE/MDR-AS-01-06.2					
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	The product does not reach the intended use, or the	2	3	NAC	1.Indicate the distributor or use to store the product by strictly follow the storage condition;	Label CE/MDR-AS-01-02	2	2	AC	No	AC

	conditions	product package will be damaged				2.Control storage / operation process						
10	Incompatibility with other devices	N/A										
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	3	2	NAC	Strengthen amending the label	Label & Instruction for Use CE/MDR-AS-01-02	3	1	AC	No	AC
2	Inadequate operating instructions	A, the inadequate operating instructions may cause misuse	2	3	NAC	Strengthen amending the operating instructions	Label & Instruction for Use CE/MDR-AS-01-02	2	2	AC	No	AC
3	Use by unskilled/untrained personnel	N/A										
4	Reasonably foreseeable misuse	A, The device can reach its	3	3	NAC	To strengthen pre-use checks and indicate the user how to use the	Instruction for Use CE/MDR-AS-01-02	3	1	AC	No	AC

		intended use.				product.							
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 or infect patient or doctor.	3	3	NA C	Indicate the usage in the user manual.	Instruction for Use CE/MDR-AS-01-02	3	1	AC	No	AC
7	Incorrect measurement and other metrological aspects	N/A											
8	Incompatibility with consumables/accessories/other devices	N/A											
9	sharp edges or points	N/A											
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 state	N/A										
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	N/A										

	information to actual state												
11	Controversial modes or mappings as compared to existing equipment	N/A											
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 adequate functional checks	2	3	NA C	1.indicate the use instructions in the user manual;	Instruction for Use CE/MDR-AS-01-02	2	2	AC	No	AC
3	Inadequate maintenance	NA											
4	Lack of adequate determination of end of device life	NA											

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	NAC	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 CE/MDR-AS-01-02	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 conductivity) as a result of repeated use.	N/A										
E.7 Production and post-production information（**Foresee**）												
1	Inadequate of designing parameters	N/A										
2	Inadequate of	N/A										

	operating parameters											
3	Inadequate of performance requirements	A, product quality will be deteriorated	3	2	NA C	Produce the product by strictly follow the QMS	Factory inspection records;	3	1	AC	No	AC
4	Insufficient control of changes to manufacturing processes	A, product quality will be deteriorated	3	2	NA C	Control the manufacturing processes by strictly follow the QMS	Quality management documents	3	1	AC	No	AC
5	Insufficient control of materials/materials compatibility information	A, product quality will be deteriorated	3	2	NA C	Chose the material which meet the requirement.	Incoming material inspection report.	3	1	AC	No	AC
6	Insufficient control of manufacturing processes	A, product quality will be deteriorated	3	2	NA C	Control the manufacturing processes by strictly follow the QMS	Quality management documents	3	1	AC	No	AC
7	Insufficient control of subcontractors	A, product quality will be deteriorated or get patient infection	3	2	NA C	Chose the material which meet the requirement.	Incoming material inspection report.	3	1	AC	No	AC
8	Lack of, or inadequate specification for, validated	NA										

	procedures for cleaning, disinfection and sterilization											
9	Inadequate conduct of cleaning, disinfection and sterilization	NA										
10	Inadequate collection post-product information	A, the product did not satisfy by the customer or could meet the requirement	2	3	NAC	collect post-product information according to QMS	Quality Procedure	2	2	AC	No	AC

Form 2. Residual risk analysis
(According to ISO/TR 24971:2020 clause 8)

SN.	Hazard code	Whether there is no further reduction in technology (economic factors are not taken into account)	Whether Risk reduction implement the regulation "as far as possible"	Whether adopting the latest technology	Whether it meets MDR GSPR	Whether the clinical benefit is greater than the risk	Whether the residual risk is acceptable	Whether the measures of reducing risk create new risks
1.	H1	yes	yes	yes	yes	yes	yes	NO
2.	H2	yes	yes	yes	yes	yes	yes	NO

3.	H3	yes	yes	yes	yes	yes	yes	NO
4.	H4	yes	yes	yes	yes	yes	yes	NO
5.	H5	yes	yes	yes	yes	yes	yes	NO
6.	H6	yes	yes	yes	yes	yes	yes	NO
7.	H7	yes	yes	yes	yes	yes	yes	NO
8.	H8	yes	yes	yes	yes	yes	yes	NO
9.	H9	yes	yes	yes	yes	yes	yes	NO
10.	H10	yes	yes	yes	yes	yes	yes	NO
11.	H11	yes	yes	yes	yes	yes	yes	NO
12.	H12	yes	yes	yes	yes	yes	yes	NO
13.	H13	yes	yes	yes	yes	yes	yes	NO
14.	H14	yes	yes	yes	yes	yes	yes	NO
15.	H15	yes	yes	yes	yes	yes	yes	NO
16.	H16	yes	yes	yes	yes	yes	yes	NO
17.	H17	yes	yes	yes	yes	yes	yes	NO
18.	H18	yes	yes	yes	yes	yes	yes	NO
19.	H19	yes	yes	yes	yes	yes	yes	NO
20.	H20	yes	yes	yes	yes	yes	yes	NO
21.	H21	yes	yes	yes	yes	yes	yes	NO

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. In one word, the risk has been managed accordingly.

6.1 Clinical Evaluation Report

File No.: CE/MDR-AS-01-06.1

Version: A/1

Product: GMDN 13913

Antiseptic swab

Prepared by		Reviewed by		Approved by	
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Position	Editor Team	**Position**	Editor Team	**Position**	Approver
Signature		**Signature**		**Signature**	

CV for Clinical evaluation team members

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 ISO14971:2019 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 Alcohol swab which is used for used for providing barrier and protection for the potentially infectious patients' blood, body fluids, secretions and airborne particles that the clinical medical personnel come into contact with while working.

The Alcohol swab is manufactured based on quality management system.

The clinical evaluation is conducted by collecting and analyzing clinical literature of the similar device of Alcohol swab search from PubMed, ScienceDirect, Google Scholar database and other literature database list in section 4.4.1. 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 Alcohol swab 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 Alcohol swab 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 Alcohol swab.

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 Alcohol swab risk analysis, the scope of this clinical evaluation comes from the intended performance and clinical residual risks in the risk analysis of these products.

2. Device description

Device Introduction
Please refer to Chapter 1 Section 1.1 about detailed device description.

Harmonized standards
- Applicable Standard
Please refer to Chapter 1 Section 1.1 about applicable standard.

Reference Guidance

Table 1. Reference Guidance

Item.	Guidance	Title
1	MEDDEV 2.12-2 rev 2 (2012)	Guidelines on post market clinical follow up
2	GHTF SG5/N2R8	Clinical Evaluation

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

The main function of the Alcohol swab is to bandage the wound, which can compress and stop bleeding. The Alcohol swab is a material used to fix or protect the surgical or injured part. Because the bandage is not sterilized, it cannot be used directly on the wound, but it can be used to wrap the gauze. You can disinfect the skin first, then stick gauze on the wound, then fix it with a bandage, and then fix it with a knot. The bandage can also be used for wounds, varicose veins, orthopedics and other diseases. Therefore, Alcohol swab play a very important role in medicine, and they are medical consumables and will be used frequently.

As an important secondary dressing, Alcohol swab will be an indispensable equipment in every hospital.

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 is 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 Alcohol swab has been sold many years. PMS data including customer feedback, customer complain, adverse event, recall and corrective actions are used in this evaluation.

4.3 PMS data of similar device

The Alcohol swab has been widely used in the world, the adverse event, recall, corrective action of the similar device is searched for a reference for the clinical safety of the propose device.

4.4 Literature search plan

4.4. 1 Literature search database

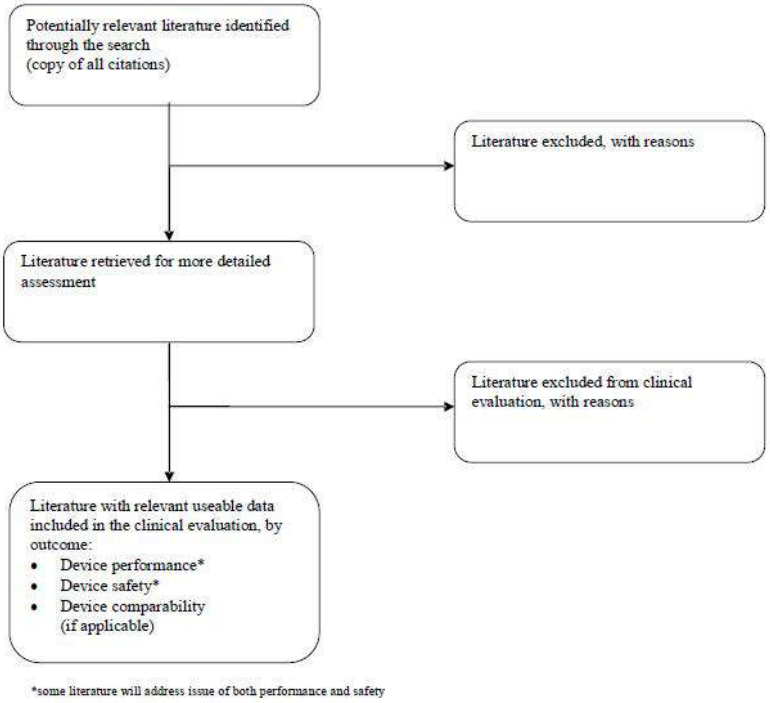
The databases used for literature search are shown as below

- Pubmed
- ScienceDirect
- CNKI

The keyword “Alcohol Prep Pads” is used 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 do not include Nonwoven 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 "Alcohol Prep Pads" as key words 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 "Alcohol Prep Pads", 1,908 literatures are found in ScienceDirect, then we review the relevance of literature and download 9 relevant literatures for review and completely review the literature, finally 3 literatures are chosen for evaluation. The search result is as below.

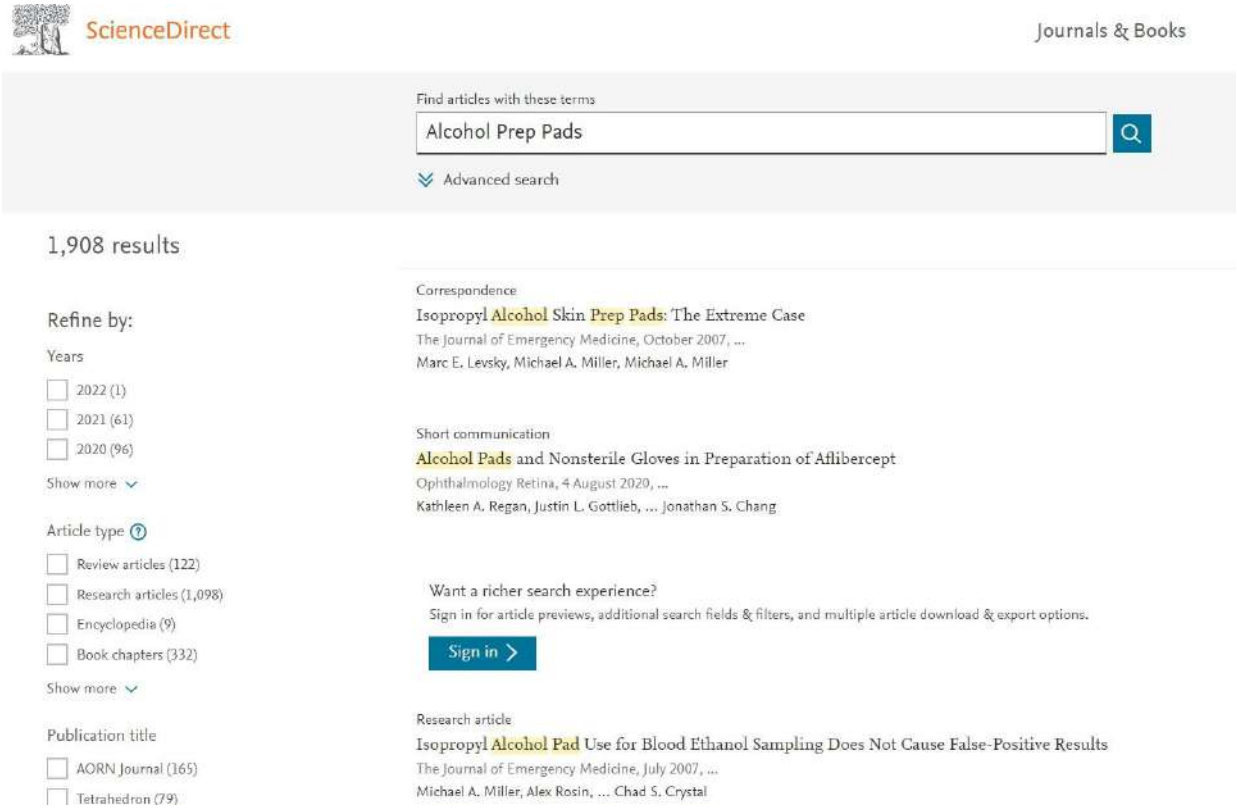


Figure 1. Search Result in ScienceDirect

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 term	Search Period	Total Literature	Relevant Literature	Literature for Clinical Evaluation
1	Pubmed	2021	Alcohol Prep Pads	2000-2020	524	7
2	Science Direct	2021		2000-2020	1,908	9
3	CNKI	2021		Not Limited	76	3

Base on the Literature search result above, there are 5 literatures are used in this clinical evaluation. Literature analysis is shown in the table below.

Table4 Literature Analysis

Item	Literature	Author& Publication	Abstract
1	Efficacy of disinfectant -impregnated wipes used for	Antimicrob Resist Infect Control. 2019; 8: 139.	“Ready-to-use” disinfecting wipes (also known as pre-impregnated disinfecting wipe) are broadly used in food industry and domestic situations. Their application in hospitals and healthcare centres for decontamination of medical devices and surfaces is

	Surface disinfection in hospitals: a review	Published online 2019 Aug 19. doi: 10.1186/s13756-019-0595-2	steadily increasing because of their convenient implementation in practice and reliable performance. Beside their acceptable compliance and easy application, literature reported the disinfection failure due to the interaction between textile substrate and active ingredients, which can highly increase the risk of an infection outbreak. This review aims to call attention to the wide range of variables affecting the disinfectant-impregnated wipes' (DIWs) disinfection performances in hospitals.
2	Wiping out MRSA: effect of introducing a universal disinfection wipe in a large UK teaching hospital	Antimicrob Resist Infect Control. 2018; 7: 155. Published online 2018 Dec 19. doi: 10.1186/s13756-018-0445-7	Contamination of the inanimate environment around patients constitutes an important reservoir of MRSA. Here we describe the effect of introducing a universal disinfection wipe in all wards on the rates of MRSA acquisitions and bacteraemias across a large UK teaching hospital.
3	Potential Allergens in Disposable Diaper Wipes, Topical Diaper Preparations, and Disposable Diapers: Under-recognized Etiology of Pediatric	JiaDe Yu 1, James Treat, Keri Chaney, Bruce Brod	Background: Allergic contact dermatitis in young children may be an under-recognized cause of perineal dermatitis. The diapered infant skin is uniquely susceptible to allergic contact dermatitis because of more permeable neonatal skin, a moist environment, frequent contact with irritants and resultant skin barrier breakdown, and exposure to topical products such as diaper wipes, diaper preparations, and disposable diapers. To our knowledge, potential allergens in these products have not been thoroughly catalogued or studied. Objective: We explore and review potential allergenic ingredients in diaper wipes, topical diaper preparations, and disposable diapers.

	Perineal Dermatitis		Method: We analyzed 63 diaper wipes, 41 topical diaper preparations, and the 3 top selling diaper brands available from two of the largest retailers in the United States. Each potential allergen is discussed, and epidemiologic studies of rates of sensitization to potential allergens in children are also reported. Conclusions: Botanical extracts, including members of the Compositae family, were the most commonly represented potential allergen in both diaper wipes and topical preparations. Other potential allergens identified with high frequency include α-tocopherol, fragrances, propylene glycol, parabens, iodopropynyl butylcarbamate, and lanolin. Frequent culprits such as formaldehyde releasers and methylchloroisothiazolinone/methylisothiazolinone were not prevalent in our analyzed products.
4	Effectiveness of cleaning-disinfection wipes and sprays against multidrug-resistant outbreak strains	Nikki Kenters 1, Elisabeth G W Huijskens 2, Sophie C J de Wit 3, Joost van Rosmalen 4, Andreas Voss	Background: Hospital rooms play an important role in the transmission of several health care-associated pathogens. During the last few years, a number of innovative cleaning-disinfecting products have been brought to market. In this study, commercially available products combining cleaning and disinfection were compared, using 2 different application methods. The aim was to determine which product was most effective in simultaneous cleaning and disinfection of surfaces. Methods: Seven cleaning-disinfecting wipes and sprays based on different active ingredients were tested for their efficacy in removal of microbial burden and proteins. Efficacy was tested with known Dutch outbreak strains: vancomycin-resistant enterococci (VRE), Klebsiella pneumoniae OXA-48, or

			Acinetobacter baumannii. Results: For all bacteria, ready-to-use cleaning-disinfecting products reduced the microbial count with a log10 reduction >5 with a 5-minute exposure time, with the exception of a spray based on hydrogen peroxide. Omitting the aforementioned hydrogen peroxide spray, there were no significant differences between use of a wipe or spray in bacterial load reduction. Using adenosine triphosphate (ATP) measurements, a significant difference in log10 relative light units (RLU) reduction between various bacteria (P ≤ .001) was observed. Conclusions: In general, a >5 log10 reduction of colony forming units (CFU) for tested wipes and sprays was obtained for all tested bacteria strains, with exception of hydrogen peroxide spray and VRE. Although ATP may show a difference between pre- and postcleaning, RLU reduction does not correlate with actual CFU reductions.
5	A review of wipes used to disinfect hard surfaces in health care facilities	John M Boyce	Background: Despite a plethora of wipes available for use in health care facilities, there is a paucity of articles describing wipe composition, potential interactions between wipes and disinfectants, the manner in which wipes are used, and their relative efficacy. The purpose of this article is to provide an in-depth review of wipes used for disinfection of hard surfaces in health care settings. Methods: Comprehensive searches of the Pubmed database and Internet were conducted, and articles published from 1953 through September 2019 and pertinent on-line

			documents were reviewed. Bibliographies of relevant articles were reviewed. Results: Wipes vary considerably in their composition, and the disinfectants with which they are used. With reusable dry wipes, the ratio of wipe material to disinfectant and the amount of disinfectant absorbed by the wipe and delivered to surfaces is difficult to standardize, which may affect their efficacy. The manner in which wipes are used by health care personnel is highly variable, due in part to insufficient instructions for use and inadequate education of relevant personnel. Conclusions: Additional research is needed regarding the best practices for using different types of wipes, improved methods for educating staff, and establishing the relative efficacy of wipes in reducing environmental contamination and health care-associated infections.

5.2 Analysis of Post-Marketing Data

The Alcohol swab has been put on market for many years and the use of Alcohol swab is mature. The actual sales quantity and the feedback may be found in clause 7.2.1 of the technical files.

The manufacture has established quality management system and strictly follow the work instructions to ensure the product quality. And the Alcohol swab has been placed on market for several years and a large number of devices has been sold. The PMS data shows the Alcohol swab is safely used on the market. The PMS data including customer feedback, customer complain are continuously collect to monitor the safety and effectiveness of Alcohol swab.

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 Alcohol swab 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 Alcohol swab 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 Alcohol swab in the claimed indications.

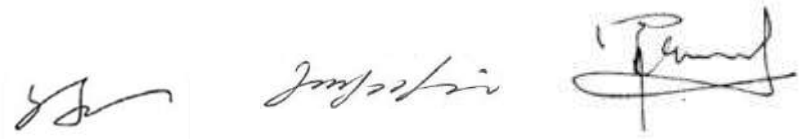
The clinical evaluation will be updated once per three years normally, but should be updated immediately if significant risk were found.

7. Declaration of interests

Sun Jinfeng, Tina Cui, Raymond Luo, are hired by the manufacturer concerned as clinical evaluator of Alcohol swab 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*



8. Reference

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6.2 Biocompatibility Compliance Evidence

File No.: CE/MDR-AS-01-06.2

Version: A/1

Product: GMDN 13913

Antiseptic swab

1. Foreword

This report is to describe the biological risk control carried on the Alcohol swab 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 Alcohol swab 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.

This device is intended to contact with patient

4.2 Categorization by duration of contact

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

as follows. 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 programmer 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 concerned 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 and Sesame Oil Extract, Intracutaneous Reactivity Test using ISO 10993-10:2010 Test Method 0.9% Sodium Chloride Injection Extract and Sesame Oil Extract were performed, all the tests results showed the concerned product possess a good biocompatibility properties.

5. Testing and test reports

Biocompatibility Evaluation Report

<table>
<tr><th>Item</th><th>Standard</th><th>Test Item</th><th>Test report</th></tr>
<tr><td>1</td><td>ISO10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity</td><td>Cytotoxicity test</td><td rowspan="3">Refer to Annex 3_Biocompatibility Test Report</td></tr>
<tr><td>2</td><td rowspan="2">ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization</td><td>Skin sensitization test</td></tr>
<tr><td>3</td><td>Skin irritation test</td></tr>
</table>

6. Conclusion

According to ISO14971 and ISO 10993-1 requirements, we have completed the biological evaluation for the Alcohol swab, the available information is sufficient to meet the purpose of the evaluation of biological safety, the Alcohol swab 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.

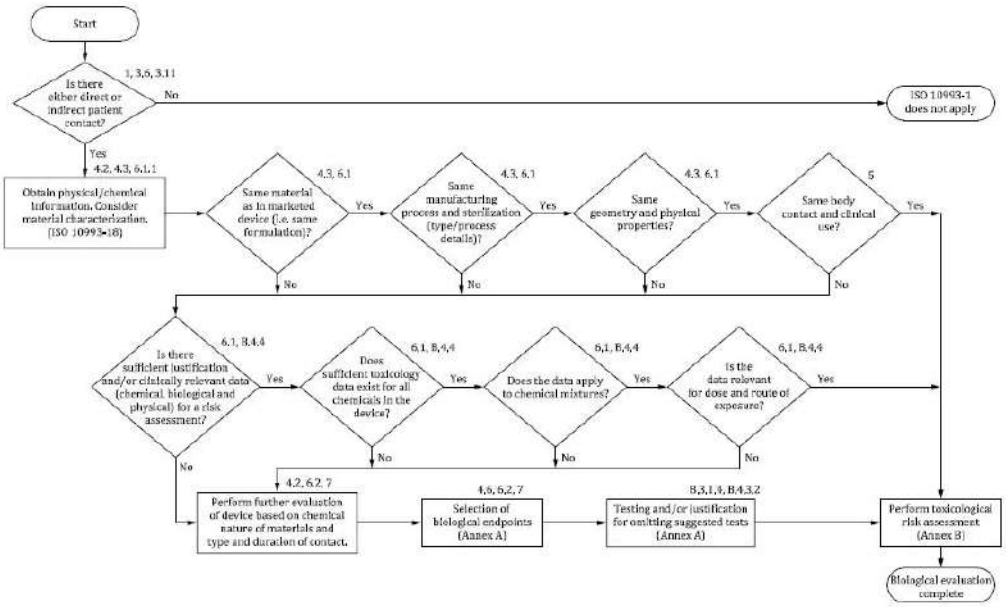

Figure 1 — Summary of the systematic approach to a biological evaluation of medical devices as part of a risk management process

6.3 Product Performance Test

The Alcohol swab should meet the quality requirements that raw material inspection and final inspection should be conducted, please refer to **Annex2_Performance Test** about the inspection and test reports.

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 Alcohol swab. Quality and Customer Service gather the customer feedbacks, and reviewing on a monthly basis.
b) 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 gathering 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

Item	PMS Method	Department	Time and frequency
1	Regular clinical evaluation	Technical Dept	Once per 3 years
2	Regular research on related literature	Technical Dept	Once per 3 years
3	Research on similar devices on the market	Sales Dept	While there is similar device put on the markets
4	Research on materials, operating principles and technologies of medical devices	Technical Dept	While there is update on the material, operating principle and technology of this product.
5	Research into new technologies	Technical Dept	While there is new technology

6	Research on product life	Technical Dept	Long-term continuous study
7	Study adverse events and establish and implement the medical device notification and withdrawal control procedures	Quality Dept	While adverse event occurs
8	Solicit relevant improvement opinions from customers, measure customer satisfaction, and establish and implement customer related process control procedures	Sales Dept	Once per year
9	Solicit relevant improvement opinions from customers, measure customer satisfaction, establish and implement customer satisfaction survey control procedure	Sales Dept	Conduct customer satisfaction survey once per year.
10	Pay close attention to the recalled products and establish and implement the medical device notification and withdrawal control procedures.	Sales Dept	While there is product recall
11	Research on new product related standards	Technical Dept	While there is product related standard updated
12	Study of new product-related regulations	Technical Dept	While there is product related standard 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 Alcohol swab customers and analysis on monthly basis.

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 in table 3. The customer feedback of the proposed device and similar device are shown in the table 2.

Table 2. Customer feedback list of the proposed device

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

Table 3. Post Market experience of similar device

Area	Time	Quantity	Complaints	Adverse events
China	2018	0	0	0
	2019	0	0	0
	2020	0	0	0
USA	2018	0	0	0
	2019	0	0	0
	2020	0	0	0
EU	2018	60,000	0	0
	2019	64,000	0	0
	2020	132,000	0	0
Total	144,400		0	0

Table 4. PMS Study Result

Item	PMS Method	Department	Data
1	Regular clinical evaluation	Technical Dept	Please refer to Clinical Evaluation Report
2	Regular research on related literature	Technical Dept	Please refer to clinical literature attached to Clinical Evaluation Report
3	Research on similar devices on the market	Sales Dept	Please refer to Clinical Evaluation Report
4	Research on materials, operating principles and technologies of medical devices	Technical Dept	No update on the material, operating principle and technology of this product.
5	Research into new technologies	Technical Dept	No new technology.
6	Research on product life	Technical Dept	No change of shelf life.
7	Study adverse events and establish and implement the medical device notification and withdrawal control procedures	Quality Dept	No, there is no adverse event occurred.
8	Solicit relevant improvement opinions from customers, measure customer	Sales Dept	No customer feedback related to product safety and quality problem.

	satisfaction, and establish and implement customer related process control procedures		
9	Solicit relevant improvement opinions from customers, measure customer satisfaction, establish and implement customer satisfaction survey control procedure	Sales Dept	Customer satisfaction survey was conducted once per year and the result shows customers are satisfied to product quality and safety.
10	Pay close attention to the recalled products and establish and implement the medical device notification and withdrawal control procedures.	Sales Dept	No products recall occurred.
11	Research on new product related standards	Technical Dept	No new product related standard.
12	Study of new product-related regulations	Technical Dept	The Europe Regulation about Regulation (EU) 2017/745 has released on 5th, May, 2017. We updated this CE technical document based on the new Medical Device Regulation (EU) 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 proposed device and similar device, the technology of Alcohol swab is mature. Risk management, bench test, literature analysis and post-market data has proven the safety and effectiveness of the proposed 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 therapy was proved to be effective. So, the benefit is higher than the risk.

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

Manufacturer

Name: Yangzhou Super Union Import & Export Co., Ltd.
Address: No.120 Xishan South Road Chenji Town 211408 Yizheng City,Yangzhou City,Jiangsu Province CHINA
SRN: CN-MF-000010954

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-AS-01.
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.

Product Information

Name: Alcohol swab

Model : 3*6CM,3*6.5CM,5*5CM,As per customer requirements
GMDN: 13913
Basic UDI-DI: 6974265590001746
Classification: Class I, According to 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: Date:10th September,2021

Position: GM Place:Yangzhou,China

SUPER UNION IMPORT&EXPORT CO.,LTD. YANGZHOU 扬州卓合进出口有限公司