CE Technical Files

BATH CHAIR

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Reviewed By	Luo Jianfang	Date	2021/03/10
Approved By	Chen Shunhong	Date	2021/03/10

Manufacturer: FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD

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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial Release	Yang Haolong	2021.03.10

Table of Contents

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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

Conformity Assessment

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

Applicable Standards
EN ISO 14971:2012
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-SC-04.

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

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

Manufacturer

Name: FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD
Address: No.168 Fusheng Rd, Fuwan Industry Area, Gaoming District, Foshan City, Guangdong, P.R. China

Product Information

Name: BATH CHAIR
Model: See Annex
GMDN: 34936
Basic UDI-DI: /
Classification: 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:

佛山市順康醫療用品有限公司
Authorized Signature(s)

Position: Place:Guangdong/China

Annex

Product Name	Model	GMDN	Basic UDI-DI
Bath seat	SC6001/SC6001-KD/SC6001Q/SC6001Q-KD SC6011Q-HD/SC6005/SC6005Q/SC6005Q-KD SC6005Q-HD/SC6010/SC6011/SC6011-KD SC6015A/SC6015A-KD/SC6015B/SC6015C SC6015C-KD/SC6020A/SC6020B/SC6020C SC6020D/SC6020E/SC6020F/SC6020G/SC6020H SC6025A/SC6025B/SC6025C/SC6025D SC6025C-W/SC6030A/SC6030A-KD/SC6030B SC6030B-KD/SC6030C/SC6030D/SC6030D-KD SC6040A/SC6040B/SC6040C/SC6040DSC6040E SC6045A/SC6045B/SC6045B-B/SC6045C SC6045C-N/SC6045D/SC6045E/SC6045F SC6050-1/SC6050-2/SC6050-3/SC6050-4 SC6055A-N/SC6055A-KD/SC6055B-N SC6055B-KD/SC6055C/SC6055D/SC6055C-KD SC6055D-KD/SC6190A/SC6190B/SC6190C SC6190E	34936	/

For and on behalf of Foshan Sunnuo Leisure Products Co., Ltd.
佛山市顺欧休闲用品有限公司

Signature: Date:

Position: ..... Place: Guangdong/China

General Safety and Performance Requirements

File No.: CE/MDR-SC-05-03

Version: A/0

Product: Bath Chair

Issued By	Reviewed By	Approved By	Effective Date
Yang Haolong	Luo Jianfang	Chen Shunhong	2021-03-10

FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD
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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
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General Safety and Performance Requirements Checklist

Item	The requirement of Medical Device Regulation (EU)2017/745	A/ NA	Standard	Evidence of Conformity
GENERAL REQUIREMENTS				
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	Label & IFU Risk Management Report: CE/MDR-SC-05-03
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-SC-05-03
3	Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall: (a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device;	A	ENISO14971：2019	Risk Management Report: CE/MDR-SC-05-03

	(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	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-SC-05-03
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	A	ENISO14971：2019	Risk Management Report:

	device and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).			CE/MDR-SC-05-03
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	ENISO14971：2019	Risk Management Report: CE/MDR-SC-05-03
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-SC-05-03
8	All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.	A	ENISO14971：2019	Risk Management Report: CE/MDR-SC-05-03
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	NA		

	related to the product's use which is consistent with a high level of protection for the safety and health of persons.			
REQUIREMENTS REGARDING DESIGN AND MANUFACTURE				
10	Chemical, physical and biological properties			
	10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: (a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability; (b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion; (c) the compatibility between the different parts of a device which consists of more than one implantable part; (d) the impact of processes on material properties; (e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; (g) surface properties; and (h) the confirmation that the device meets any defined chemical and/or physical specifications.	A	ENISO15223-1:2016 EN1041:2008+A1：2013	Label & IFU
	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	A	ENISO15223-1:2016	Label & IFU

	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.		EN1041:2008+A1：2013	
	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 be (re)administered to the body, shall only contain the following substances in a concentration that is above	A	ENISO14971：2019	Risk Management Report: CE/MDR-SC-05-03

	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	NA		

	includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.			
	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		
	10.4.4. Guidelines on other CMR and endocrine-disrupting substances Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.	NA		
	10.4.5. Labelling Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence	A	ENISO15223-1:2016 EN1041:2008+A1：2013	Label & IFU

	of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.			
	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-SC-05-03
	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-SC-05-03
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	A	ENISO14971：2019	Risk Management Report: CE/MDR-SC-05-03

	(d) prevent microbial contamination of the device or its content such as specimens or fluids.			
	11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	A	ENISO15223-1:2016 EN1041:2008+A1：2013	Label & IFU
	11.3. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	NA		
	11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.	NA		
	11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	NA		
	11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	NA		
	11.7. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	NA		

	11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.	NA		
12	Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.	NA		
	12.1. In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.	NA		
	12.2. Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.	NA		
13	Devices incorporating materials of biological origin	NA		
	13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall	NA		

	apply: (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; (b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; (c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.			
	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	NA		

	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			
	13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In 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.	NA		
14	Construction of devices and interaction with their environment	NA		
	14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.	NA		
	14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the	NA		

	volume/pressure ratio, dimensional and where appropriate ergonomic features; (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; (c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use; (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; (e) the risks of accidental ingress of substances into the device; (f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and (g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
	14.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	NA		
	14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	NA		
	14.5. Devices that are intended to be operated together with other devices or	NA		

	products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.			
	14.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.	NA		
	14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.	NA		
15	Devices with a diagnostic or measuring function	NA		
	15.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.	NA		
	15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC	NA		
16	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,	NA		

	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.			
	16.2. Intended radiation (a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. (b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.	NA		
	16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.	NA		
	16.4. Ionising radiation (a) Devices intended to emit ionizing radiation shall be designed and	NA		

	manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. (b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. (c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. (d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.			
17	Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves	NA		
	17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.	NA		
	17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance	NA		

	with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.			
	17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).	NA		
	17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	NA		
18	Active devices and devices connected to them	NA		
	18.1. For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.	NA		
	18.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.	NA		
	18.3. Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.	NA		
	18.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's	NA		

	state of health.			
	18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.	NA		
	18.6. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.	NA		
	18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, 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		
	18.8. Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.	NA		
19	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:	NA		

	— excessive increase of leakage currents, — ageing of the materials used, — excess heat generated by the device, — decreased accuracy of any measuring or control mechanism.			
	19.2. Active implantable devices shall be designed and manufactured in such a way as to ensure — if applicable, the compatibility of the devices with the substances they are intended to administer, and — the reliability of the source of energy.	NA		
	19.3. Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.	NA		
	19.4. Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.	NA		
20	Protection against mechanical and thermal risks			
	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.	A	EN ISO14971:2012	Label & IFU
	20.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	NA		

	20.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	NA		
	20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.	NA		
	20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	NA		
	20.6. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	NA		
21	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		
	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	NA		

	prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.			
	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.	A	EN ISO14971:2012	Label &IFU
22	Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	NA		
	22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.	NA		
	22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to: — ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information, — reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and — reduce as far as possible the risk of error by the intended user in the handling of the device and, if	NA		

	applicable, in the interpretation of the results.			
	22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: — can verify that, at the time of use, the device will perform as intended by the manufacturer, and — if applicable, is warned if the device has failed to provide a valid result.	NA		
	REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE			
23	Label and instructions for use	A	ENISO15223-1:2016 EN1041:2008+A1：2013	Label & IFU
	23.1. General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following: (a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. (b) The information required on the label shall be provided on the device	A	ENISO15223-1:2016 EN1041:2008+A1：2013	Label & IFU Printed label and IFU was used.

	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 form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.			

	23.2. Information on the label The label shall bear all of the following particulars: (a) the name or trade name of the device; (b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device; (c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; (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	A	ENISO15223-1:2016 EN1041:2008+A1：2013	Label & IFU

	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; (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.			
	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	NA		

	device safely expressed at least in terms of year and month, and (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.			
	23.4. Information in the instructions for use The instructions for use shall contain all of the following particulars: (a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2; (b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate; (c) where applicable, a specification of the clinical benefits to be expected. (d) where applicable, links to the summary of safety and clinical performance referred to in Article 32; (e) the performance characteristics of the device; (f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories; (g) any residual risks, contra-indications and any undesirable side-effects,	A	ENISO15223-1:2016 EN1041:2008+A1：2013	Label & IFU

	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 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 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 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; (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.			

Risk Management Report

Company Name:	FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD
Company Address:	NO.168 Fusheng Rd, Fuwan Industry Area, Gaoming District, Foshan City, Guangdong, P.R.China
Product:	Bath Chair
Document No.:	CE/MDR-SC-05-04
Version:	A/0
Accessories:	N/A
Procedure:	EN ISO 14971：2019
CONCLUSION:	All risks associated with the identified hazards have been evaluated considering EN ISO14971 The overall level of risk of the product is acceptable. After appropriate measures to reduce these risks have been taken, the overall risks (all risks together) have been deemed acceptable versus the benefit of the device.

Prepared by		**Checked by**		**Approved by**	
Name	Yang Haolong	**Name**	Luo Jianfang	**Name**	Chen Shunhong
Position	Tech. Manager	**Position**	M.R.	**Position**	G.M.
Date	2021/03/10	**Date**	2021/03/10	**Date**	2021/03/10

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial Release	Yang Haolong	2021-03-10

Chapter One Review

1. Product Introduction

Bath Chair is used as bathing tools for people with disabilities, patients and the elderly who are difficult to maintain balance while showering.

1.1 Product Name

Bath Chair

1.2 Product Function

For people with disabilities, patients and the elderly who are difficult to maintain balance while showering.

1.3 Product Picture, Configuration and Material

Figure 1. Photo of Bath Chair

The configuration of Bath Chair please refer to file CE/MDR-SC-05-01.

2. Standard List

No.	File No.	File Title
1	Regulation (EU) 2017/745	Medical Device Regulation
2	MEDDEV 2 12-1 Rev:8	Vigilance report form for field safety corrective action report Form Manufacturer's Field Safety Corrective Action Report
3	MEDDEV. 2.7.1 Rev.4	Clinical evaluation: A guide for manufacturers and notified bodies

4	EN ISO 14971:2019	Medical Device -Application of Risk Management in Medical Device
5	EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
6	EN 1041:2008+A1:2013	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
7	ISO 10993-1:2018	Biological evaluation of medical devices---part 1: Evaluation and testing
8	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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
General Manager	1. Responsible for approving the risk management plan and risk management report; 2. Responsible for providing the necessary resource conditions for risk management measures.
Manager representative	1. Participate in risk management activities, review risk management plans and reports; 2. Responsible for organizing risk management review; 3. Assist the person in charge of the enterprise to organize and coordinate risk management activities.
Sales	1. Responsible for collecting customer usage information feedback after product sales; 2. Responsible for reporting bad information to the scientific research department; 3. Implementation of product recall actions, implementation of advisory notification actions.
Technology Department	1. Formulation of risk management plan; 2. Preparation of risk management report; 3. Follow-up and effectiveness verification of risk control measures; 4. Regular update and retention of risk management reports.
Purchasing Department	1. Participate in risk management activities; 2. Implement work related to this department in risk management measures.
Production Department	1. Participate in risk management activities; 2. Implement the work related to the department in the risk management measures; 3. Assist the technical department to verify the effectiveness of the measures.
Quality Department	1. Participate in risk management activities; 2. Implement work related to this department in risk management measures. 3. Assist the technical department to verify the effectiveness of the measures.

5. Risk Management Plan

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 Chapter three.

6) Activities related to the collection and evaluation of information related to the production and production after production–Refer to the Chapter five.

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 ISO 14971. Its task is to describe the risk management process for the following product:

Commode Chair to identify potential risks, evaluate them and to control them effectively. This risk management plan describes the risk management process of the medical device manufacturer:

FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD 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

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

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	$\geq 10^{-3}$

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 (acc.to Accord to ISO/TR24971:2020,A2)

Item	Question	Answer
1	A.2.1 What is the intended use and how is the medical device to be used?	
2	A.2.2 Is the medical device intended to be implanted?	
3	A.2.3 Is the medical device intended to be in contact with the patient or other persons?	
4	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?	
5	A.2.5 Is energy delivered to or extracted from the patient?	
6	A.2.6 Are substances delivered to or extracted from the patient?	

7	A.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	
8	A.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	
9	A.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	
10	A.2.10 Does the medical device intended to modify the patient environment?	
11	A.2.11 Are measurements taken?	
12	A.2.12 Is the medical device interpretative?	
13	A.2.13 Is the medical device intended for use in conjunction with other medical device, medicines or other medical technologies?	
14	A.2.14 Are there unwanted outputs of energy or substances?	
15	A.2.15 Is the medical device susceptible to environmental influences?	
16	A.2.16 Does the medical device influence the environment?	
17	A.2.17 Does the medical device require consumables or accessories?	
18	A.2.18 Is maintenance or calibration necessary?	
19	A.2.19 Does the medical device contain software?	
20	A.2.20 Does the medical device allow access to information.	
21	A.2.21 Does the medical device store data critical to patient care?	
22	A.2.22 Does the medical device have a restricted shelf-life?	
23	A.2.23 Are there any delayed or long-term	

	use effects?	
24	A.2.24 To what mechanical forces will the medical device be subjected?	
25	A.2.25 What determines the lifetime of the medical device?	
26	A.2.26 Is the medical device intended for single use?	
27	A.2.27 Is safe decommissioning or disposal of the medical device necessary?	
28	A.2.28 Does installation or use of the medical device require special training or special skills?	
29	A.2.29 How will information for safe use be provided?	
30	A.2.30 Are new manufacturing processes established or introduced?	
30	A.2.30 Is successful application of the medical device critically dependent on usability the user interface?	
31	A.2.31.1 Can the user interface design features contribute to use error?	
32	A.2.31.2 Is the medical device used in an environment where distractions can cause use error?	
33	A.2.31.3 Does the medical device have connecting parts or accessories?	
34	A.2.31.4 Does the medical device have a control interface?	
35	A.2.31.5 Does the medical device display information?	
36	A.2.31.6 Is the medical device controlled by a menu?	
37	A.2.31.7 Is the successful use of the medical device dependent on a user's knowledge, skills abilities?	
38	A.2.31.8 Will the medical device be used by persons with specific needs?	

39	A.2. 31.9 Can the user interface be used to initiate user actions?	
40	A.2.32 Does the medical device use an alarm system?	
41	A.2.33 In what ways might the medical device be deliberately misused(deliberately or not)?	
42	A.2.34 Is the medical device intended to be mobile or portable?	
43	A.2.35 Does the use of the medical device depend on essential performance?	
44	A.2.36 Does the medical device have a degree of autonomy	
45	A.2.37 Does the medical device produce an output that is used as an input in determine 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 Annex B.

Step 1: Intended Use and Identification of Characteristics Related to the Safety of the Medical Device

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, Appendix C of the current standard EN ISO 14971:2019 is applied.

Step 2: Identification of Hazards

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

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

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

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

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

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

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

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

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

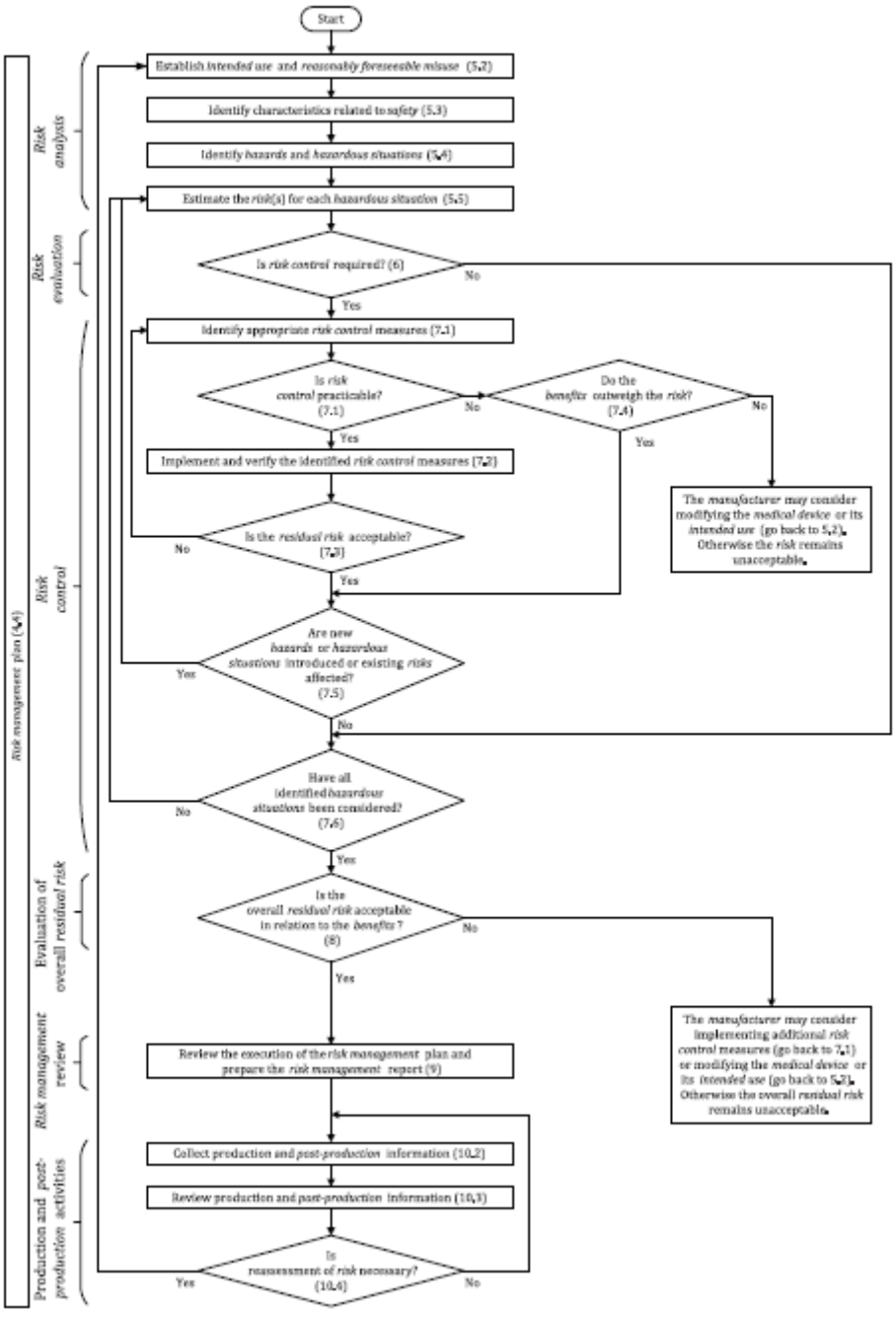
There will be a summarizing risk management report. It will summarize the risk analysis, risk evaluation and management of preventive respectively risk control measures. This risk management report will be set up and released at least once per year by the management or its deputy

Step13: Production and post-production information

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

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 (acc.to Accord to ISO24971:2020,A2)

Item	Question	Answer
1	A.2.1 What is the intended use and how is the medical device to be used?	See Instruction for Use
2	A.2.2 Is the medical device intended to be implanted?	NO.
3	A.2.3 Is the medical device intended to be in contact with the patient or other persons?	Contact the user directly
4	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?	Yes. Main material PP, Aluminum alloy
5	A.2.5 Is energy delivered to or extracted from the patient?	NO.
6	A.2.6 Are substances delivered to or extracted from the patient?	NO.
7	A.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO.
8	A.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO.
9	A.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	Cleaning and maintenance is needed.
10	A.2.10 Does the medical device intended to modify the patient environment?	NO.

11	A.2.11 Are measurements taken?	NO.
12	A.2.12 Is the medical device interpretative?	NO.
13	A.2.13 Is the medical device intended for use in conjunction with other medical device, medicines or other medical technologies?	NO.
14	A.2.14 Are there unwanted outputs of energy or substances?	NO.
15	A.2.15 Is the medical device susceptible to environmental influences?	NO.
16	A.2.16 Does the medical device influence the environment?	NO.
17	A.2.17 Does the medical device require consumables or accessories?	NO.
18	A.2.18 Is maintenance or calibration necessary?	NO.
19	A.2.19 Does the medical device contain software?	NO.
20	A.2.20 Does the medical device allow access to information.	NO.
21	A.2.21 Does the medical device store data critical to patient care?	NO.
22	A.2.22 Does the medical device have a restricted shelf-life?	NO.
23	A.2.23 Are there any delayed or long-term use effects?	NO.
24	A.2.24 To what mechanical forces will the medical device be subjected?	NO.
25	A.2.25 What determines the lifetime of the medical device?	The aging of material will affect the lifetime.
26	A.2.26 Is the medical device intended for single use?	NO.
27	A.2.27 Is safe decommissioning or disposal of the medical device necessary?	Dispose the waste of products to comply with local regulations.
28	A.2.28 Does installation or use of the	NO.

	medical device require special training or special skills?	
29	A.2.29 How will information for safe use be provided?	Label, Instruction for use.
30	A.2.30 Are new manufacturing processes established or introduced?	NO.
30	A.2.30 Is successful application of the medical device critically dependent on usability the user interface?	NO.
31	A.2.31.1 Can the user interface design features contribute to use error?	NO.
32	A.2.31.2 Is the medical device used in an environment where distractions can cause use error?	NO.
33	A.2.31.3 Does the medical device have connecting parts or accessories?	NO.
34	A.2.31.4 Does the medical device have a control interface?	NO.
35	A.2.31.5 Does the medical device display information?	NO.
36	A.2.31.6 Is the medical device controlled by a menu?	NO.
37	A.2.31.7 Is the successful use of the medical device dependent on a user's knowledge, skills abilities?	NO.
38	A.2.31.8 Will the medical device be used by persons with specific needs?	NO.
39	A.2. 31.9 Can the user interface be used to initiate user actions?	NO.
40	A.2.32 Does the medical device use an alarm system?	NO.
41	A.2.33 In what ways might the medical device be deliberately misused(deliberately or not)?	NO.
42	A.2.34 Is the medical device intended to be mobile or portable?	Yes, it is portable.
43	A.2.35 Does the use of the medical device depend on essential performance?	NO.

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

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 patient	N/A										

16	Ultrasonic energy	N/A											
17	Infrasound energy	N/A											
18	Sound	N/A											
19	High pressure fluid injection	N/A											
E.2 Biological and Chemical Hazards													
1	Bacteria	The product may be contaminated with bacteria if the not properly packaged.	2	3	NAC	Design proper packaging of products for protection.	Packaging design	2	2	AC	No	AC
2	Viruses	There are virus if the product is not maintain and clean regularly.	3	3	NAC	Indicate the user to maintain and clean the product on time.	Instruction for use	3	1	AC	No	AC
3	Other agents (e.g. prions)	N/A											
4	Re- or cross-infection	N/A											
5	Acids or alkalis	N/A											
6	Residues	N/A											
7	Contaminates	If the device is failed to be	2	3	NAC	Indicate the cleaning method on label and	Label and Instruction for Use.	2	2	AC	No	AC

		cleaned as required, it may cause the patient infected by bacteria				Instruction for Use.						
8	additives or processing aids	N/A										
9	cleaning, disinfecting or testing agent	If the device is failed to be cleaned as required, it may cause the patient infected by bacteria	2	3	NAC	Indicate the cleaning method on label and Instruction for Use.	Label and Instruction for Use.	2	2	AC	No	AC
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, users will fill uncomfortable if the materials do	3	3	NAC	Choose raw material with good biocompatibility.	Incoming inspection report	3	1	AC	No	AC

		not possess good biocompatibility										
15	Allergenicity	N/A										
16	irritancy	N/A										
17	Pyrogenicity	N/A										
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	N/A										

	conditions											
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	Inadequate labeling may lead to improper operation of the user during use, and cause abnormal functions of the device and cause damage.	2	3	NAC	Design the label to ensure label information comply with the requirements of the General Safety and Performance Requirements.	Label	2	2	AC	No	AC
2	Inadequate operating instructions	Incomplete information in the instruction for use, such as insufficient	2	3	NAC	Write the Instruction for Use to comply with the requirements of the General Safety and Performance	Instruction for Use	2	2	AC	No	AC

		precaution of safe use, too complicated operating instructions, unreasonable recommended maintenance methods may lead to improper operation of the user during use, and cause abnormal functions of the device and cause damage.				Requirements.						
3	Use by unskilled/untrained personnel	N/A										
4	Reasonably foreseeable misuse	Mistakenly operation may cause unexpected damage of the device.	3	2	NAC	Design the label with warning information to ensure label information comply with the requirements of the General Safety and	Label	3	1	AC	No	AC

						Performance Requirements.						
5	Insufficient warning of side effects	The device maybe used for other purpose and hurt the user.	3	2	NAC	Present the intended use and warnings in the instruction for use.	Instruction for use.	3	1	AC	No	AC
6	Inadequate warning of hazards likely with re-use of single use devices	N/A										
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	N/A										

	errors											
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,	N/A										

	audibility or tactility											
10	Poor mapping of controls to action, or of displayed information to actual state	N/A										
11	Controversial modes or mappings as compared to existing equipment	N/A										
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 before use.	2	3	NAC	1.indicate the use instructions in the user manual.	Instruction for Use	2	2	AC	No	AC

3	Inadequate maintenance	The user may feel uncomfortable, get infected or even hurt by the device if they do not maintain the device on time.	3	2	NAC	Indicate in the instruction for use that the device shall be maintain on time.	Instruction for Use	3	1	AC	No	AC
4	Lack of adequate determination of end of device life	User may be hurt by the device if they use the device after the expiration date.	3	2	NAC	Indicate the shelf life in the instruction for use.	Instruction for Use	3	1	AC	No	AC
5	Loss of electrical / mechanical integrity	N/A										
6	Inadequate packaging(contamination and /or deterioration of the device)	The lifetime of the device may be affected if the product package may be damaged.	2	3	NAC	1.Package the product by strictly follow the QMS 2.Indicate the user do not use the product if the package damaged.	1.Product release inspection records, 2. Instruction for Use	2	2	AC	No	AC
7	re-use and / or	A, user may be	3	2	NAC	1.Indicate in the	Instruction for Use	3	1	AC	No	AC

	Improper re-use	harmed if they don't re-use the device properly.3				instruction for use that maintain and clean the device on time;2. Pre-check the device before use;3. Do not use the device after the expiry dated.						
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 operating parameters	N/A										
3	Inadequate of performance requirements	A, product quality will be affected	3	2	NAC	Package the product by strictly follow the QMS	Factory inspection records, Product performance	3	1	AC	No	AC

							test report					
4	Insufficient control of changes to manufacturing processes	A, product quality will be affected	3	2	NAC	Control the manufacturing processes by strictly follow the QMS	Quality Procedure	3	1	AC	No	AC
5	Insufficient control of materials/materials compatibility information	A, product quality will be affected or hurt patient	3	2	NAC	Chose the material which meet the requirement.	1.Biocompatibility Test Report 2.Incoming material inspection report.	3	1	AC	No	AC
6	Insufficient control of manufacturing processes	A, product quality will be affected	3	2	NAC	Control the manufacturing processes by strictly follow the QMS	Quality Procedure	3	1	AC	No	AC
7	Insufficient control of subcontractors	A, product quality will be affected or hurt patient	3	2	NAC	Chose the material which meet the requirement.	1. Biocompatibility Test Report 2. Incoming material inspection report.	3	1	AC	No	AC
8	Lack of, or inadequate specification for, validated procedures for cleaning,	A, product quality will be affected or hurt patient.	3	2	NAC	Indicate the user to clean the device on time.	Instruction for use.	3	1	AC	No	AC

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

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.

Clinical Evaluation Report

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<Manufacture: FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD >
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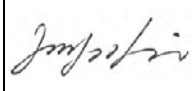
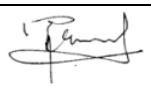
Signature		**Signature**		**Signature**	

Product name: Bath Chair
Classification of product: I, according to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745
Manufacturer: FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD
Address: NO.168 Fusheng Rd, Fuwan Industry Area, Gaoming District, Foshan City, Guangdong, P.R.China

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 ISO14971:2012 training course, provided by BSI.

Raymond Luo	From 2004.3 to present, get more than 10 years' experience on the medical device global regulation compliance in global famous certification body and consulting organization. **Major: Biological engineering** 2004.3 to 2015.3 Production certification director and the manager of the international business unit, manage the business of the global product certification including CE marking and all the certification business in Asia Pacific, which covers 14 countries besides China. 2015.3 to Present Act as the technical manager of SUNGO Technical Service Inc., responsible for the medical device compliance consulting, covers US and EU regulations.

Table of Contents

Executive summary

This clinical evaluation report presents the clinical evaluation of Bath Chair which is used as bathing tools for people with disabilities, patients and the elderly who are difficult to maintain balance while showering.

Bath Chair manufactured by FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD is made of Aluminum Alloy and so on, it's manufactured basing on quality management system.

The clinical evaluation is conducted by collecting and analyzing clinical literature of the similar device of Bath Chair search from PubMed, ScienceDirect 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 Bath Chair 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 Bath Chair 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 Bath Chair.

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 Bath Chair 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

Bath Chair is used as bathing tools for people with disabilities, patients and the elderly who are difficult to maintain balance while showering.

The Bath Chair is made of PE, PU, Aluminum alloy and other materials. There are several models of Bath Chair which can meet different requirements. The product pictures are shown as below.

Figure 1. Photo of Bath Chair

Intended use

Bath Chair is used as bathing tools for people with disabilities, patients and the elderly who are difficult to maintain balance while showering.

Model

The model and specifications are shown in the table below

Table 1. Product Description

MODEL	Photo	Material	Size H*W*D (cm)	Package (pc/ctn)
SC6001		Aluminum+plastic	49*39*39	1PC/CTN
SC6001-KD		Aluminum+plastic	49*39*39	1PC/CTN

SC6001Q		Aluminum+plastic	49*39*39	1PC/CTN
SC6001Q-KD		Aluminum+plastic	49*39*39	1PC/CTN
SC6001Q-HD		Aluminum+plastic	49*39*39	1PC/CTN
SC6005		Aluminum+plastic	49*51*69	1PC/CTN
SC6005Q		Aluminum+plastic	49*51*69	1PC/CTN
SC6005Q-KD		Aluminum+plastic	49*51*69	1PC/CTN
SC6005Q-HD		Aluminum+plastic	49*51*69	1PC/CTN
SC6010		Aluminum+plastic	49*51*69	1PC/CTN
SC6011		Aluminum+plastic	49*58*36	1PC/CTN
SC6011-KD		Aluminum+plastic	49*58*36	1PC/CTN
SC6015A		Aluminum+plastic	49*58*36	1PC/CTN

SC6015A-KD		Aluminum+plastic	41*38*33	1PC/CTN
SC6015C		Aluminum+plastic	41*38*33	1PC/CTN
SC6015B		Aluminum+plastic	41*38*33	1PC/CTN
SC6015C-KD		Aluminum+plastic		1PC/CTN
SC6020A		Aluminum+plastic	32*32*35	1PC/CTN
SC6020B		Aluminum+plastic	32*32*35	1PC/CTN
SC6020C		Aluminum+plastic	58*58*34	1PC/CTN
SC6020D		Aluminum+plastic	32*32*35	1PC/CTN
SC6020E		Aluminum+plastic	32*32*35	1PC/CTN
SC6020F		Aluminum+plastic		1PC/CTN

SC6020G		Aluminum+plastic		1PC/CTN
SC6020H		Aluminum+plastic		1PC/CTN
SC6025A		Aluminum+plastic	51*43*48	1PC/CTN
SC6025B		Aluminum+plastic	51*43*48	1PC/CTN
SC6025C		Aluminum+plastic		1PC/CTN
SC6025D		Aluminum+plastic		1PC/CTN
SC6025C-W		Aluminum+plastic		1PC/CTN
SC6030A		Aluminum+plastic	77*53*81	1PC/CTN
SC6030B		Aluminum+plastic	77*53*81	1PC/CTN

SC6030A-KD		Aluminum+plastic	77*53*81	1PC/CTN
SC6030B-KD		Aluminum+plastic	77*53*81	1PC/CTN
SC6030C		Aluminum+plastic	68*49*84	1PC/CTN
SC6030D		Aluminum+plastic	68*49*84	1PC/CTN
SC6040A		Aluminum+plastic	50*52*81	1PC/CTN
SC6040B		Aluminum+plastic	55*52*80	1PC/CTN
SC6040C		Aluminum+plastic	73*52*35	1PC/CTN
SC6040D		Aluminum+plastic	61*58*47	1PC/CTN
SC6040E		Aluminum+plastic	73*52*60*78	1PC/CTN

SC6045A		Aluminum+plastic	73*23*18	1PC/CTN
SC6045B		Aluminum+plastic	80*42*23	1PC/CTN
SC6045B-B		Aluminum+plastic		1PC/CTN
SC6045C		plastic	70*5*36	1PC/CTN
SC6045C-N		plastic	77*5*36	1PC/CTN
SC6045D		plastic	77*7*36	1PC/CTN
SC6045E		plastic	92*5*37.5	1PC/CTN
SC6045F		plastic	90*5*37	1PC/CTN
SC6050-1		Aluminum+plastic	48*27*50	1PC/CTN
SC6050-2		Aluminum+plastic	48*50*60	1PC/CTN

SC6050-3		plastic	48*9*40	1PC/CTN
SC6050-4		Aluminum+plastic	40*48*30	1PC/CTN
SC6055B-N		Aluminum+plastic	51*44*85	1PC/CTN
SC6055B-KD		Aluminum+plastic	51*44*85	1PC/CTN
SC6055A		Aluminum+plastic	51*44*73	1PC/CTN
SC6055A-KD		Aluminum+plastic	51*44*73	1PC/CTN
SC6055C		Aluminum+plastic	51*44*85	1PC/CTN

SC6055D		Aluminum+plastic	51*44*85	1PC/CTN
SC6055C-KD		Aluminum+plastic	51*44*85	1PC/CTN
SC6055D-KD		Aluminum+plastic	51*44*85	1PC/CTN
SC6190A		Aluminum+plastic	50*31*38	1PC/CTN
SC6190B		Aluminum+plastic	50*31*38	1PC/CTN
SC6190C		Aluminum+plastic		1PC/CTN

SC6190E		Aluminum+plastic	50*31*38	1PC/CTN

Basic UDI-DI

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

SRN

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

Patient Population

The Bath Chair can be used for people with a variety of disabilities, patient and elderly.

Contraindications

Nil

Instruction for Use

1. Before use, adjust the bath seat to a suitable height, so that four feet are on the ground smoothly.
2. Check whether the backrest is installed firmly and whether there is a swing during use. Please sit in the middle of the shower chair during use.
3. The height of the bath seat can be adjusted. When adjusting the height, first push down the marbles, and then pull it down. Just adjust to the height suitable for your own use.

Maintenance

1. Routinely clean and disinfect once a day by medical staff or users, and thoroughly disinfect the chair when changing patients.
2. Do not contact with strong acids and alkalis to prevent corrosion.

Warnings：

- Please do not support on one side when getting up or sitting down, to prevent the shower chair from being overturned and injured.
- Use it with care on uneven ground. Please clean and disinfect the bath chair in time.
- This product is safe to use with a load of 136kg. Be careful when using it in excess of this weight, or it can be customized by the company.

Storage

The product should be stored in normal temperature and humidity and keep dry.

Shelf Life

5 years.

Disposal

Dispose the waste of products to comply with local regulations.

Applicable Standard

Table 2. Applicable Standard

No.	File No.	File Title
1	Regulation (EU) 2017/745	Medical Device Regulation
2	MEDDEV 2 12-1 Rev:8	Vigilance report form for field safety corrective action report Form Manufacturer's Field Safety Corrective Action Report
3	MEDDEV. 2.7.1 Rev.4	Clinical evaluation: A guide for manufacturers and notified bodies
4	EN ISO 14971:2019	Medical Device -Application of Risk Management in Medical Device
5	EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
6	EN 1041:2008+A1:2013	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
7	ISO 10993-1:2018	Biological evaluation of medical devices---part 1: Evaluation and testing
8	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Table 3. 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 Bath chair is also known as bath seat, shower seat. It is very commonly used in hospital, and home for the disable or who has difficulties in showing. A bath chair can be placed inside your bathtub or shower. It allows you to safely sit on the chair while you wash your body. Bath chairs help users who have difficulty sitting in a standard bath tub or standing in a shower.

4. Identification of relevant clinical data

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

4.1 Literature Data

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

4.2 PMS data generated and held by Manufacture

The propose device Bath Chair has been sold for several 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 Bath Chair has been widely used in the world, we will search for the adverse event, recall, corrective action of the similar device for a reference for the clinical safety of the propose device.

4.4 Literature search plan

4.4. 1 Literature search database

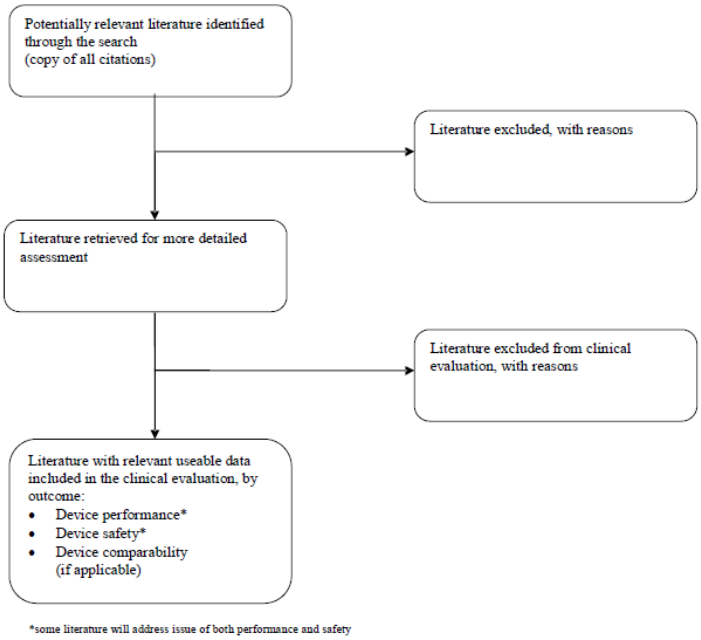
The databases used for literature search are shown as below

- Pubmed
- ScienceDirect
- CNKI

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

4.4.2 Literature selection criteria

The literature selection criteria process is as follow:



We select the relevant literature according to the device discussed in the article, if the device is similar to the propose device, we will choose that literature for evaluation. If the device has similar intended use, the same work mechanism to the propose device, the device will be deemed as the similar device.

4.4.3 Literature exclusion criteria

We will review all articles’ title and/or abstracts, if the article do not include bath chair 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 “Bath Chair” as key word to search relevant literatures 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 “Bath Chair”, 17,803 literatures are found in ScienceDirect, then we review the relevance of literature and download 5 relevant literature for review and completely review the literature, finally 1 literature are chosen for evaluation. The search result is as below.

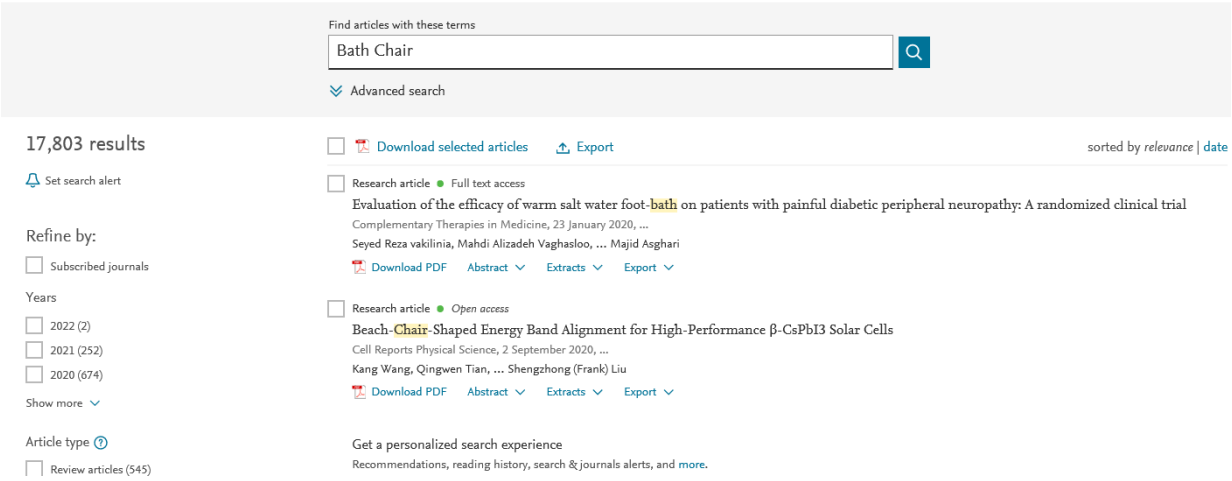


Figure 2. Search Result in ScienceDirect

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

Table 5. Literature Collection in different Database

Item	Database	Search Date	Search term	Search Period	Total Literature	Relevant Literature	Literature for Clinical Evaluation
1	Pubmed	03/04/2021	Bath Chair	Not limited	642	5	2
2	Science Direct	03/04/2020		2000-2020	17803	5	1
3	CNKI	03/04/2020		2000-2020	183	5	3

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

Table 6. Literature Analysis

Item	Author / Literature/ Publication	Abstract
1	Chinese social work. Elder.2014.09.Pg42-49 **The choice of bath chair for older adults** LUO Yi-min	Abstract Choosing an elderly bath chair, the most important thing is to consider the smoothness of the elderly sitting in the chair, the way to get in and out of the bathroom, the standing and movements in bathroom. Also, the space of the bathroom should be considered.
2	2017, No.10 STANDARD SCIENCE**.** Research on Standard Application. **A**	Abstract: This paper introduces the concept and function of the elderly assistive technology and the adaptation assessment of the old appropriate aids, elaborates the functional assessment and dysfunction assessment, analyzes the main purpose of dysfunction assessment, and puts forward that the elderly assistive technology and utilization effect assessment should

	Probe into the Elderly Assistive Technology and Modern Pension Rehabilitation LUO Yi-min	contain personal factor, environmental factor, technical factor and activity factor. Keywords: elderly assistive technology, dysfunction assessment, pension rehabilitation
3	2018, No.5 STANDARD SCIENCE**.** Research on Standard Application. **Assistive Aids for the Elderly and Modern Geriatric Care.** LUO Yi-min	Abstract: The paper introduces the auxiliary function and classification of assistive aids for the elderly, and explains the application of these assistive aids in geriatric care including functional care beds, wheelchairs, potty chairs, shower chairs, mobile carts, support armrest, life self-help, etc. Combined with appropriate space environment, it proposes a principle on how to configure assistive aids for the elderly that is “adaptation first, then evaluation” and “compensate first, then replace, adapt”. Keywords: assistive aids for the elderly, geriatric care, adaption
4	Disabil Rehabil Assist Technol. 2013 Jul;8(4):267-74. **Clinical assessment, design and performance testing of mobile shower commodes for adults with spinal cord injury: an exploratory review.** Friesen E[1], Theodoros D, Russell T.	Abstract PURPOSE: The purpose of this article is to explore evidence concerning clinical assessment, design and performance testing of mobile shower commodes used by adults with spinal cord injury (SCI). METHOD: Searches of electronic databases, conference proceedings and key journals were undertaken with no restriction on language or study design. Keywords included spinal cord injury, lesion, sanichair, sanitary chair, shower chair, bowel chair and commode. RESULTS: A total of 20 publications were included in this review. Common approaches to clinical assessments were questionnaires and observational analysis to assess bowel care routines, function and skin integrity. Design features addressed access for bowel care, postural support, transfers, stability, use in wet environments and skin integrity. Objective performance measures addressed requirements for static stability, backward-sloping seat angles, arm supports and seat materials. CONCLUSIONS: Evidence reviewed was of low methodological quality and lacking in validated instruments to guide clinical practice. Further high-quality research is needed to identify bathing, showering and personal hygiene tasks affecting mobile shower commodes use and to develop validated clinical assessment tools. Performance

		testing to published standards is also needed.
5	Occup Ther Health Care. 1996;10(1):41-59. **Usage and effectiveness of rails, bathing and toileting AIDS.** Clemson L[1], Martin R.	Abstract There is a lack of systematic follow-up on the usage or effectiveness of rails and aids to elderly persons or persons with disability. One hundred and forty-four persons, mostly elderly, responded to a mailed questionnaire. Factors associated with usage and non-usage of commonly used bathing and toileting aids and rails, and rails used for access to and from the home were investigated, including reasons for non-usage, equipment acceptance, perceived benefit, ergonomic factors and equipment reliability. The questionnaire was shown to have high internal consistency. Usage rates were high, 86% for rails and 76% for aids. Non-usage was largely attributed to change in functional status. There were also some specific areas of dissatisfaction indicated, including issues of aid prescription, methods of assessing rail placement, and design of equipment.
6	J Safety Res. 2019 Jun;69:69-73. doi: 10.1016/j.jsr.2019.02.003. Epub 2019 Feb 25. **When bathing leads to drowning in older adults.** Guay M[1], D'Amours M[2], Provencher V[3].	Abstract INTRODUCTION: Bathing is the most problematic activity of daily living for aging adults, and the ability to perform it is influenced by physical capabilities that decrease with age. Drowning is an under-documented event related to bathing for older adults. This study investigates the circumstances of these tragedies, to prevent them. METHODS: Census of 2005-2014 bathtub drownings in the province of Quebec (Canada) involving victims aged 65+. Coroner's reports were analyzed using a grid based on factors previously associated with bath-related drownings in literature, iteratively modified. RESULTS: Among the 92 bathtub drowning victims inventoried, 42% were aged 65+. The average age of older victims is 79 (65-97, ±9 years). Main probable cause of drowning is a cardiac problem, although only 19% of victims had a medical history of heart disease. Most victims were alone in their apartment or residence when drowning occurred. Risky periods appear to be springtime, Sundays, and evenings. Despite expectations, relevant information about the physical environment is very scarce. CONCLUSIONS: At least 39 Quebecers, aged 65+, drowned in their bathtubs over a 10-year period. More older adults than children are victims of

		bathtub drownings in community-dwellings. It seems that bathing may induce heart distress, leading to an appreciable number of drownings. PRACTICAL IMPLICATIONS: Since cardiac health problems are present in these deplorable events, promoting access to safety devices in the environment (emergency button, grab bars) and modified personal hygiene habits (bathing chair, showering) might be potential ways to prevent drowning and improve safety in older adults while they perform their personal hygiene, an essential activity for health and human dignity.

5.2 Analysis of Post-Marketing Data

The Bath Chair has been placed on the market for several years. Over the past 3 years, we have sold 260,122 pcs of Bath Chair to overseas market and received 0 case of customer complains about product safety. The customer feedback of the propose device and similar device are shown in the table below.

Table 7. Post Market experience of propose device

Area	Time	Quantity	Complaints	Adverse events
China	2017	6830	0	0
	2018	8462	0	0
	2019	10720	0	0
USA	2017	6830	0	0
	2018	8462	0	0
	2019	10720	0	0
EU	2017	54642	0	0
	2018	67696	0	0
	2019	85760	0	0
Total	260,122		0	0

Table 8. Customer feedback list of the propose device in 2018-2019

NO.	Description	Root Cause	Corrective actions	states
1	/	/	/	/

The Bath Chair manufactured by FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD is intended to be used as bathing tools for people with disabilities, patients and the elderly who are difficult to maintain balance while showering. The device has been sold in many countries for many years and the use of Bath Chair is mature. The manufacture has established quality

management system and strictly follow the work instructions to ensure the product quality. And the Bath Chair has been placed on market for several years and a large number of devices has been sold. The PMS data shows the Bath Chair is safety use on the market. The PMS data including customer feedback, customer complain are continuously collected to monitor the safety and effectiveness of Commode Chair.

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 Bath Chair is low and acceptable. This clinical evaluation is complied with MDR (EU) 2017/745.

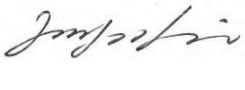
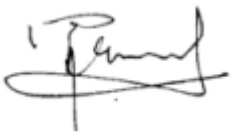
6.Next Clinical Evaluation

As extensively outlined above, the use of Bath Chair 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 Bath Chair 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 FOSHAN SUNCARE MEDICAL PRODUCTS CO., LTD as clinical evaluator of Bath Chair from 01/01/2021 to 06/01/2021 to participate in the clinical evaluation. In order to ensure the validity and impartiality of clinical evaluation. We make a declaration of interests as follow.

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

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

8. Reference

[1] *Chinese social work. Elder.2014.09.Pg42-49 The choice of bath chair for older adults LUO Yi-min*

[2] *2017, No.10 STANDARD SCIENCE. Research on Standard Application. A Probe into the Elderly Assistive Technology and Modern Pension Rehabilitation LUO Yi-min*

[3] *2018, No.5 STANDARD SCIENCE. Research on Standard Application. Assistive Aids for the Elderly and Modern Geriatric Care. LUO Yi-min*

[4] *Disabil Rehabil Assist Technol. 2013 Jul;8(4):267-74.*
Clinical assessment, design and performance testing of mobile shower commodes for adu lts with spinal cord injury: an exploratory review. Friesen E[1], Theodoros D, Russell T.

[5] *Occup Ther Health Care. 1996;10(1):41-59.*
Usage and effectiveness of rails, bathing and toileting AIDS. Clemson L[1], Martin R.

[6] *J Safety Res. 2019 Jun;69:69-73. doi: 10.1016/j.jsr.2019.02.003. Epub 2019 Feb 25. When bathing leads to drowning in older adults. Guay M[1], D'Amours M[2], Provencher V[3].*

Biological Evaluation Report

File No.: CE/MDR-SC-05-06

Version: A/0

Product: Bath Chair

Issued By	Reviewed By	Approved By	Effective Date
Yang Haolong	Luo Jianfang	Chen Shunhong	2021.03.10

Foshan Suncare Medical Products Co., Ltd.

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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	-	Yang Haolong	2021.03.10

1. Foreword

This report is to describe the biological risk control carried on the Bath Chair 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 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 Bath Chair 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

These include medical devices in contact with the following.

Table 1. Components materials and duration

Components	Raw material	Contact/ non-contact	Duration
Chair	PE(Polyethylene),PP(Polypropylene),PU(Poluurethane),PVC(Polyvinyl Chloride)	Contact with human tissue	< 24 hours
Handrail	Aluminum alloy	Contact with human tissue	< 24 hours

The information of raw material are shown as below.

Table2. Raw Material details

Material	Physical Property	Chemical Property
Polyethylene(PE)	Polyethylene resin is a non-toxic, odorless white powder or granule, with a milky white appearance, a wax-like feel, and a low water absorption rate of less than 0.01%. Polyethylene film is transparent and decreases with increasing crystallinity.	CAS#: 9002-88-4 Melting point 92 °C Boiling point 48-110 °C(Press: 9 Torr) density 0.962 g/mL at 25 °C Fp 270 °C storage temp. ?20°C form powder color White Specific Gravity 0.95 Water Solubility Soluble in acetone and benzene. Insoluble in water. Merck 14,7567 Stability: Stable, but breaks down slowly in uv light or sunlight. Incompatible with halogens, strong oxidizing agents, benzene, petroleum ether, aromatic and chlorinated hydrocarbons, lubricating oils. PE is chemically stable and resistant to most acids and bases (not resistant to acids with oxidizing properties). Insoluble in common solvents at room temperature, low water absorption and excellent electrical insulation.
Polypropylene (PP)	Polypropylene is a low-density	CAS#:9003-07-0

	resin that offers a good balance of thermal, chemical, and electrical properties, along with moderate strength. Strength can be significantly increased by using reinforcing agents such as glass fiber. Polypropylene has limited heat resistance, but it can be used in applications that must withstand boiling water or steam sterilization.	Polypropylenes can resist chemical attack and are unaffected by aqueous solutions of inorganic salts or mineral acids and bases, even at high temperatures. They are not attacked by most organic chemicals, and there is no solvent for these resins at room temperature. The resins are attacked, however, by halogens, fuming nitric acid, other active oxidizing agents, and by aromatic and chlorinated hydrocarbons at high temperatures . Polypropylene is translucent and autoclavable. Properties can be improved by compounding with fillers, by blending with synthetic elastomers, and by copolymerizing with small amounts of other monomers.
Polyurethane(PU)	Polyurethane is a resilient, flexible and durable manufactured material that can take the place of paint, cotton, rubber, metal or wood in thousands of applications across virtually all fields. It can be hard like fiberglass, squishy like upholstery foam, protective like varnish, bouncy like rubber or sticky like glue.Polyurethane formulations cover an extremely wide range of stiffness, hardness, and densities. It seals surfaces such as wood, metal and paint to protect them from rot, corrosion or fading. As an adhesive, polyurethane resists moisture and heat, so it is ideal for use in the sun or underwater. It also insulates walls, temperature-controlled vehicles and consumer coolers.	CAS #:9009-54-5 A polyurethane, commonly abbreviated PU, is any polymer consisting of a chain of organic units joined by urethane (carbamate) links. Polyurethane polymers are formed through step-growth polymerization by reacting a monomer containing at least two isocyanate functional groups with another monomer containing at least two hydroxyl (alcohol) groups in the presence of a catalyst.
Polyvinyl chloride(PVC)	Polyvinyl chloride, commonly abbreviated PVC, is the thirdmost	CAS #:9002-86-2 Melting point:170-195 °C (decomp)

	widely produced plastic, after polyethylene and polypropylene. PVC is used in construction because it is more effective than traditional materials such as copper, iron or wood in pipe and profile applications. It can be made softer and more flexible by the addition of plasticizers, the most widely used being phthalates. In this form, it is also used in clothing and upholstery, electrical cable insulation, inflatable products and many applications in which it replaces rubber.	Boiling point:0.100 °C Density 1.4 g/mL at 25 °C(lit.) refractive index: n 1.54 form: powder Specific Gravity1.385 Stability:Stable. Combustible. Incompatible with strong oxidizing agents. Indirect Additives used in Food Contact Substances POLY(VINYL CHLORIDE)
Aluminium/aluminium alloy	Aluminum is a light metal, small density (2.79 / Cm3), has good strength and plastic, aluminum alloy has good strength, super-hard aluminum alloy strength of 600 mpa, the tensile strength of ordinary hard aluminum alloy is 200-450 mpa, its degrees than steel is far higher than that of steel, therefore widely used in machinery manufacturing. Second only to the conductivity of aluminium silver and copper, in the third place, used in the manufacture of all kinds of wires. Aluminum has good thermal conductivity, can be used for a variety of cooling material. Aluminium has good corrosion resistance and good plasticity, suitable for all kinds of pressure processing. The addition of an alloying element to aluminum can change its structure and properties and make it suitable for various machining materials or casting parts. Frequently added alloy elements are copper, magnesium, zinc, silicon. Aluminum alloy can be	Aluminum is a silver-white light metal. It's malleable. Merchandise is often made into bar, sheet, foil, powder, ribbon and filamentous. In moist air an oxide film can be formed to prevent metal corrosion. Aluminum powder and aluminum foil burn fiercely in the air with heat and produce a blinding white flame. Soluble in dilute sulfuric acid, nitric acid, hydrochloric acid, sodium hydroxide and potassium hydroxide solution, insoluble in water. Relative density 2.70. Melting point is 660 ℃. The boiling point of 2327 ℃. Aluminum alloys usually use copper, zinc, manganese, silicon, magnesium and other alloying elements

	divided into binary and multiple platform gold. In a binary alloy with Al, Cu and Al - Si alloy is the most widely applied. According to the technological characteristics of aluminum alloy, and it can be divided into two categories, casting aluminum alloy and deformation of aluminum alloy. Commonly used aluminum alloy deformation is made of aluminum alloy.	

4.1 Categorization by duration of contact

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

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

The framework for the development of an assessment programmed 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 informa-tion	Cyto toxi city		Irrita tion or intra cuta neous reac tivity	Ma-terial media ted pyro geni city[a]	Acute syste mic toxi city[b]	Sub acu te toxi city[b]	Sub chro nic toxi city[b]	Chr onic toxi city[b]	Impla nta tion ef-fects-[b,c]	Hem oco mpa tibil ity	Gen otox ici-ty[d]	Car cin oge nic ity[d]	Repro duc-tive/ develop mental toxici-ty[d,e]	Deg rada tion[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.

Literature showed raw material possesses good performance. We demonstrated the biological safety of the Bath Chair through the literature below.

Table 3. Literature search

Literature (Polypropylene (PP))	**Abstract**	**Conclusion**
Author: HAN Rong , Yan bin , ZHANG Tongcheng , ZHANG Yonghong Title: Studies on Biocompatibility of Biomedical Materials Publication: Journal of Soochow University (Medical Edition) 2010; 30 (4), DOI: CNKI: SUN: SYXU.0.2010-04-032	Abstract : Objective To evaluate the biocompatibilities of four species of biomedical materials. Methods According to the standard of the ISO 10993, the bioc0mpatibilities of the biomedical materials were evaluated by using the cell cytotoxic test , sensitization test , intracutaneous stimulation tests, acute toxicity test, hemolysis test, implantation test , chromosomal aberration tests, micronucleus tests, Ames tests and pyrogen tests. Results The qualification rate of the biomedical metals ,	The pass rates of cytotoxicity test, sensitization test, intradermal stimulus test and pyrogen test of biomedical polymer materials were 62.16%, 99.70%, 99.69%, and 95,000%, respectively. The qualified rates of cytotoxicity test, sensitization test, intradermal stimulus test, hemolysis test and pyrogen test of medical dressings were 99.39%, 99.69%, 99.34%, 97.50% and 96. 27%, the pass rate of the remaining biocompatibility tests is 100%. The study showed that PE possesses good

	biomedical polymers , medical dressings and other materials was 98．63％ , 89．40％ , 99．91％ and 99 . 63 ％ respectively．Conclusion Four species of biomedical materials all have good biocompatibility.	biocompatibility.
Authors:Liang Huigang, Huang Ke Title:The development status and trend of biomedical polymer materials. Publication: Advanced Materials Industry 2016 (2) :12-15	With the progress of science and technology, the improvement of living standards, the improvement in human health, which has given rise to many new needs, such as the development of artificial organ, artificial joints, slow release drugs, etc. The emergence of these requirements has led to a combination of biology, medicine, chemistry, physics and materials science, and the emergence of biomedical materials. Biological medical materials consume less raw materials, energy saving and environmental protection, and high added value of technology. It is a typical strategic emerging industry that has maintained annual growth rate of over 20 percent in the last 10 years. In the case of China's gradual population aging society and the increasing demand for trauma, biomedical materials will usher in a new round of rapid development.	In the case of China's gradual population aging society and the increasing demand for trauma, biomedical materials will usher in a new round of rapid development. This paper mainly focuses on the biological macromolecule material which is very important in biomedical materials. PP material has good biocompatibility and meet the requirements of ISO10993 series standards. Its worth to use in clinic.

Literature(PE)	Abstract	Conclusion

Author: HAN Rong , Yan bin , ZHANG Tongcheng , ZHANG Yonghong Title: Studies on Biocompatibility of Biomedical Materials Publication: Journal of Soochow University (Medical Edition) 2010; 30 (4), DOI: CNKI: SUN: SYXU.0.2010-04-032	Abstract：Objective To evaluate the biocompatibilities of four species of biomedical materials. Methods According to the standard of the ISO 10993，the bioc0mpatibilities of the biomedical materials were evaluated by using the cell cytotoxic test，sensitization test，intracutaneous stimulation tests，acute toxicity test，hemolysis test，implantation test，chromosomal aberration tests，micronucleus tests，Ames tests and pyrogen tests. Results The qualification rate of the biomedical metals , biomedical polymers，medical dressings and other materials was 98．63％ , 89．40％ , 99．91％ and 99．63％ respectively. Conclusion Four species of biomedical materials all have good biocompatibility.	The pass rates of cytotoxicity test, sensitization test, intradermal stimulus test and pyrogen test of biomedical polymer materials were 62.16%, 99.70%, 99.69%, and 95,000%, respectively. The qualified rates of cytotoxicity test, sensitization test, intradermal stimulus test, hemolysis test and pyrogen test of medical dressings were 99.39%, 99.69%, 99.34%, 97.50% and 96. 27%, the pass rate of the remaining biocompatibility tests is 100%. The study showed that PE possesses good biocompatibility.
Author: Liang Huigang, Huang Ke; Title: Development status and trends of biomedical polymer materials Publication: New Materials Industry, 2016, 000 (002): 12-15.DOI： CNKI:SUN:XCLY.0.2016-02-005	With the advancement of science and technology and the improvement of living standards, human health requirements are also increasing, which has led to many new needs, such as the development of artificial organs, artificial bone joints, and slow-release drugs. The emergence of these needs has led to the multi-disciplinary integration of biology, medicine, chemistry, physics, and materials science, and biomedical materials have emerged as the times require. Biomedical materials consume less raw materials, save energy and protect the environment,	Biomedical polymer materials, as materials implanted in the human body, must meet the complexities of the human body. Environment, so there are strict requirements for the performance of the material. First, the material must not be toxic and can not cause deformity; second, it is relatively biocompatible and cannot react with the human body; third, it has strong chemical stability and is not easy to decompose; fourth, it has certain physical and mechanical properties; Fifth,

	and have high value-added technology. They are typical strategic emerging industries and have maintained an annual growth rate of more than 20% in the past 10 years. With China's gradual aging of the society and increasing demand for trauma recovery, biomedical materials will usher in a new round of rapid development. This article focuses on a very important class of biomedical materials-biopolymer materials.	it is easier to process; finally, it is cost-effective. One of the most critical properties is biocompatibility. According to the International Standards Organization (ISO) Release, biocompatibility refers to the situation in which living tissues respond to inactive materials after they enter. condition. After the biological material is implanted into the human body, the biological material and the specific biological tissue environment interact with each other and this effect will continue until the equilibrium is reached or the implant is removed. Biocompatibility includes histocompatibility, cytocompatibility, and blood compatibility.
Author: HUANG Jing-huan,DING Jian-dong Title: Biomedical Polymeric Materials and Modern Medical Sicence Publication: China Medical Device Information * Volume 10, N0. 4, 2004	Biomedical polymeric materials have been of the increasing importance for human health. and much progress has been made during the latest decade. Their broad applications have been classified and their specific requirements have been reviewed. Some new development was also briefly introduced.	Medical polymer materials have the following good chemical and biological properties, (1) biological functionality: they vary with the use of various biological materials, but they must all perform the desired function or induce the expected response when implanted in the body, such as : When used as a slow-release drug, the drug's slow-release properties; (2) Biocompatibility: can be summarized as the relationship between the material and the living body, mainly including blood

		compatibility (Anticoagulant) and histocompatibility (non-toxic, non-allergenic, non-genotoxic, non-carcinogenic, non-pyrogenic, immune rejection, etc.); (3) chemical stability: resistant to biological aging (Specially stable) or biodegradable (controllable degradation); (4) Processability: can be formed and sterilized (ultraviolet sterilization, high pressure boiling, ethylene oxide gas sterilization, alcohol sterilization, etc., has been widely used In the medical device industry.
Literature(Polyurethane(PU))	**Abstract**	**Conclusion**
Author: HUANG Jing-huan,DING Jian-dong Title: Biomedical Polymeric Materials and Modern Medical Sicence Publication: China Medical Device Information * Volume 10, N0. 4, 2004	Biomedical polymeric materials have been of the increasing importance for human health. and much progress has been made during the latest decade. Their broad applications have been classified and their specific requirements have been reviewed. Some new development was also briefly introduced.	Medical polymer materials have the following good chemical and biological properties, (1) biological functionality: they vary with the use of various biological materials, but they must all perform the desired function or induce the expected response when implanted in the body, such as : When used as a slow-release drug, the drug's slow-release properties; (2) Biocompatibility: can be summarized as the relationship between the material and the living body, mainly including blood compatibility (Anticoagulant) and histocompatibility (non-toxic, non-allergenic, non-genotoxic, non-carcinogenic, non-pyrogenic, immune rejection, etc.); (3) chemical

		stability: resistant to biological aging (Specially stable) or biodegradable (controllable degradation); (4) Processability: can be formed and sterilized (ultraviolet sterilization, high pressure boiling, ethylene oxide gas sterilization, alcohol sterilization, etc., has been widely used In the medical device industry.
Authors: Dong-Tsamn Lin, Tai-Horng Young*, Yu Fang Title: Studies on the e!ect ofsurface properties on the biocompatibility of polyurethane membranes Publication: Biomaterials 22 (2001) 1521}1529	To study the effect of surface properties on the biocompatibility of biomaterials based on the same material, polyurethane membranes with different surface properties were prepared. Myoblast culture and interleukin-1 (IL-1) generation in an air pouch model and in vitro monocyte culture were used to examine biocompatibility of different polyurethane membranes. Polyurethane membranes were found to exhibit signi"cant di!erences depending on their surface properties prepared by di!erent fabrication processes. When myoblasts were cultured on polyurethane surfaces, the smooth and hydrophobic membrane (F1), prepared by the solvent evaporation process, showed the greatest inhibition ofmyoblast adhesion compared with other porous and hydrophilic membranes (F2, F3 and F4), prepared by immersing the polymer solution into a precipitation bath. In contrast, IL-1 generation by monocytes/macrophages on the	The interaction of biomaterials with various cells is discussed in this study. The study showed that PU possesses good biocompatibility.

	membrane F1 was more severe than those on the porous and hydrophilic membranes. Based on our results, the interaction ofbiomaterials with various cells is discussed.	

Literature(Polyvinyl chloride (PVC))	**Abstract**	**Conclusion**
Author: HAN Rong , Yan bin , ZHANG Tongcheng , ZHANG Yonghong Title: Studies on Biocompatibility of Biomedical Materials Publication: Journal of Soochow University (Medical Edition) 2010; 30 (4), DOI: CNKI: SUN: SYXU.0.2010-04-032	Abstract：Objective To evaluate the biocompatibilities of four species of biomedical materials. Methods According to the standard of the ISO 10993，the bioc0mpatibilities of the biomedical materials were evaluated by using the cell cytotoxic test，sensitization test，intracutaneous stimulation tests，acute toxicity test，hemolysis test，implantation test，chromosomal aberration tests，micronucleus tests，Ames tests and pyrogen tests. Results The qualification rate of the biomedical metals , biomedical polymers，medical dressings and other materials was 98．63％ ，89．40％ ，99．91％ and 99．63％ respectively. Conclusion Four species of biomedical materials all have good biocompatibility.	The pass rates of cytotoxicity test, sensitization test, intradermal stimulus test and pyrogen test of biomedical polymer materials were 62.16%, 99.70%, 99.69%, and 95,000%, respectively. The qualified rates of cytotoxicity test, sensitization test, intradermal stimulus test, hemolysis test and pyrogen test of medical dressings were 99.39%, 99.69%, 99.34%, 97.50% and 96. 27%, the pass rate of the remaining biocompatibility tests is 100%. The study showed that PE possesses good biocompatibility.
Authors:A.J. BEREJKA Title: MATERIALS USED IN MEDICAL DEVICES Publication: Anthony J. Berejka on 05 February 2016	The medical device area benefits from the availability of numerous commercially available polymeric raw materials. Sophisticated product design,and not the materials, contributes more to the overall product C08t. Thefprudent	The medical device area benefits from the availability of numerous commercially available polymeric raw materials.

	design of a disposable medical device should take into account pricevolume relationships that exist for all raw materials. While some polymer chemistry, such as urethane and acrylic chemistry, lends itself to diverse manipulation, it would be more cost effective to develop products based on knownfand proven raw materials, rather than to formulate and synthesize materials offsmaller volume demand. Often such marginal changes in materials can be overcome by a more fundamental understanding of the properties of existing raw materials. In all cases, when radiation sterilization is being considered, the effects of radiation on the polymers themselves must be taken into account.	

Literature (Aluminium alloy)	**Abstract**	**Conclusion**
Academic department of Chinese journal of tissue engineering research and clinical rehabilitation Title: Application status and development trend of medical metal materials related products Publication: Journal of Clinical Rehabilitative Tissue Engineering Research December 17, 2010 Vol.14, No.51	Medical metallic materials used as biomedical materials are metals and alloys used as biomedical materials. They are biological inert materials and the most widely used implant materials in clinical practice. It is mainly used for the repair and replacement of hard tissues such as bone and teeth, cardiovascular and soft tissue repair, and structural components in the manufacture of artificial organs. The medical metal	There are many kinds of metal materials, but few of them can meet the requirements of long-term service under the conditions of human physiological environment. After long-term research and clinical screening, the biomedical metal materials widely used in clinical treatment mainly include medical stainless steel, medical drill-based alloy, medical

	materials used in clinic mainly include stainless steel, base alloy, titanium base alloy and porous metal. Medical devices made from it are implanted into the body and have the function of treating, repairing, replacing or enhancing human tissues or organs. Metal materials have been used in medicine for a long time, and have been used in human body implants for more than 400 years.	titanium and titanium alloy, medical shape memory alloy and medical magnetic alloy. In particular, the advantages of medical titanium and titanium alloy materials have been recognized by the medical community.
Authors: Chen Xioyong Title:Introduction to present situation and application of shape memory alloy Publication: CNKI:SUN:SHGA.0.1988-01-011	Shape memory and metal functional materials Since its discovery, more than 50 kinds of alloys have been reported to have memory effect, but only the nickel-titanium alloy and the copper-base copper-zinc aluminum alloy and copper-aluminium-nickel alloy have been applied. Nickel-titanium shape memory alloys are characterized by excellent strength, toughness, wear resistance, corrosion resistance, superelasticity, repeated use stability and biological compatibility. However, the high cost and high activity of titanium make it difficult to produce, so the application of this kind of alloy is limited.	Shape memory alloy should be widely used in medicine, almost all kinds of medical departments, such as internal medicine, surgery, plastic, gynecology, ophthalmology, otolaryngology, dentistry and so on. There is also a wide variety of equipment made from shape memory alloys and its worth to use in clinic.

5. Conclusion

According to ISO14971 and ISO 10993-1 requirements, the literature list in section 4, we have completed the biological evaluation for the Bath Chair, the available

information is sufficient to meet the purpose of the evaluation of biological safety, the Crutches biological risks are acceptable.