Technical Construction File

(File No.ShengboCE2)

Version: A/0

Disposable vaginal speculum

According to

Medical Directive 93/42/EEC

Issued Date:Dec.15, 2015

Yuhuan County Shengbo Mould Manufacturing Co., Ltd.

Western of Chinese Sterile Medical Equipment Base,Qinggang Town,Yuhuan County,Zhejiang Province, China.

TEL: +86-576-86106537 FAX: +86-576-86106537

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Content

No.	Doc. No.	Doc. Name	Ver.	Effective date
Part A				
1	ShengboCE2 -01	Declaration of Conformity	A/0	Nov..05, 2015
2	ShengboCE2 -02	Brief Introduction	A/0	Nov..05, 2015
3	ShengboCE2 -03	List of Harmonized Standard	A/0	Nov..05, 2015
4	ShengboCE2 -04	Essential Requirements Checklist	A/0	Nov..20, 2015
5	ShengboCE2 -05	Risk Analysis Report	A/0	Nov..05, 2015
6	ShengboCE2 -06	Product Descriptions	A/0	Nov..25, 2015
7	ShengboCE2 -07	Label and Packaging	A/0	Nov..05, 2015
8	ShengboCE2 -08	Instruction for Use	A/0	Nov..05, 2015
9	ShengboCE2 -09	Preclinical Assessment	A/0	Nov..05, 2015
10	ShengboCE2 -10	Packaging Qualification Summary	A/0	Nov..05, 2015
11	ShengboCE2 -11	Sterilization Verification Summary	A/0	Nov..05, 2015
Part B				
12	ShengboCE2 -12	Clinical Evaluation	A/0	Nov..20, 2015
13	ShengboCE2 -13	Production and Quality Control	A/0	Nov..05, 2015
14	Appendix.1	EC Authority Representative Agreement		
15	Appendix.2	Product Biocompatibility Reports		
16	Appendix.3	Packaging Qualification Report		
17	Appendix.4	Sterilization Validation Report		

Declaration of Conformity

Manufacturer	**Yuhuan County Shengbo Mould Manufacturing Co., Ltd. Western of Chinese Sterile Medical Equipment Base,Qinggang Town,Yuhuan County,Zhejiang Province, China.**
European Representative:	**KINGSMEAD SERVICE LIMITED 145-157 St John Street, London, EC1V 4PY (UK)**
Product Name:	**Disposable vaginal speculum**
Type:	S, M, L
UMDNS Code:	11267

Classification (MDD, Annex IX): **I sterile, rule 5**

Conformity Assessment Route: **Annex V.**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
NB Identification number:	0123
(EC) Certificate(s):	
Expire date of the Certificate:	
Start of CE Marking:	
Place, Date of Issue:	**Yuhuan, 2015-12-15**
Signature:	
Name:	**Alan Zhou**
Position:	**General Manager**

Product introduction

1. Introduction of the company

Yuhuan County Shengbo Mould Manufacturing Co., Ltd.was set up in 1998, main products of disposable medical equipment, the company is located in Yuhuan Qing Hong Kong Science and Technology Industrial Park in the region, with the current domestic most advanced production and testing equipment, the factory received a number of honorary title, the company management in accordance with the ISO9001:2008 requirements, inspection staff all through the national testing center of training and obtain the certificate, the company introduced the latest high-tech equipment, design CAD/CMA Taiwan CNC machining center, CNC electrical pulse, line cutting computer injection machine. The main products are : medical equipment, industrial products, electrical appliances, plastic mold and plastic products. Products are exported to Southeast Asian countries and other countries and regions, by the users trust and praise.

The quality control system according to the relative China National Standard and International Standard and also the production facility. The inprocess control and finish products quality meets to the relative China National Standard and ISO standard. We have the timely marketing research information system and the RD department is available for the different clients of their requirements. Shengbo will be the well know company and brand world wide in nearly future for its quality products and service.

Contact information:

Yuhuan County Shengbo Mould Manufacturing Co., Ltd.
Western of Chinese Sterile Medical Equipment Base,Qinggang Town,Yuhuan County,Zhejiang Province, China.
TEL: +86-576-86106537 FAX: +86-576-86106537

The authorized representative of European Union:

KINGSMEAD SERVICE LIMITED
145-157 St John Street, London, EC1V 4PY (UK)
Tel/Fax: 044-20-32399738

2. Product brief introduction

Product name: Disposable vaginal speculum

Intended use: Vaginal Speculum is used for inspecting the vagina of clinic patient. Choose suitable specification Vaginal Speculum, push the closed Vaginal Speculum into vagina and to the place which need to be inspected, fix and screw down the bolt then inspect.

Materials: PS,PC,PE

Product Name	Disposable vaginal speculum
UMDNS code	11267
Type	S, M, L
Sterilization	EO
Validity	5 years
The Manual	ShengboCE2-08, Version:A/0

3 Classification of the product

According to the requirements of the intended use of the product and MDD 93/42/EEC:
Product name: Disposable vaginal speculum
Classification: The above products belong to Class I sterile medical devices according to Rule 5 of Classification in Annex IX of MDD 93/42/EEC.

4 Application method

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC as amended by 2007/47/EC and the product apply CE certification following the instruction from Annex V.3+VII.

5 Notified body

TÜV SÜD Product Service GmbH,
Ridlerstr. 65, 80339 München, Germany

Chapter 3. List of harmonized standard

List of European Union Harmonized Standards which this produt applies.

Standard/Directive	Name of document
93/42/EEC	Medical device directive
EN 980:2008	Symbols for use in the labeling of medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 556-1:2001/AC: 2006	Sterilization of medical devices- Requirements for medical devices to be designated "STERILE"-Part 1: Requirements for terminally sterilized medical devices
EN 556-2:2003	Sterilization of medical devices- Requirements for medical devices to be designated "STERILE"-Part 2: Requirements for aseptically processed medical devices
EN ISO 10993-1:2009+ AC:2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity
ENISO 10993-7:2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010	Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly process
EN ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods-Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices- Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11135-1:2007	Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN 62366:2008	Medical devices - Application of usability engineering to medical devices

EN ISO 14644-1:1999	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness
EN ISO 14644-2:2000	Cleanrooms and associated controlled environments -- Part 2: Specifications for testing and monitoring to prove continued compliance with EN ISO 14644-1
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Bio-contamination control -- Part 1: General principles and methods
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments -- Bio-contamination control -- Part 2: Evaluation and interpretation of bio-contamination data
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices.
MEDDEV. 2.7.1 Rev.3	Clinical evaluation: A guide for manufacturers and notified bodies

Product name:
产品名：
Disposable Vaginal Speculums

Type(s)/Model(s):
类型/型号
L, M, S

Product group:
产品族
N.A

Issue date of Technical File:
技术文档发布日：
2015.11.20

Revision of Technical File:
技术文档修订版本：
A/0

Legal Manufacturer:
法定制造商

Yuhuan County Shengbo Mould Manufacturing Co., Ltd.
Name 名字

Western of Chinese Sterile Medical Equipment Base,Qinggang Town
Street 街道

317606 (*Postal code 邮编*) Yuhuan county,Zhejiang Province (*Place 地点*)

China
Country 国家

Accessories:
附件：
N.A

2015.11.20		
Date 日期	*Name Preparer/编写人的名字*	*Signature Preparer /编写人签字*
2015.11.20		
Date 日期	*Name Reviewer /审核人的名字*	*Signature Reviewer /审核人签字*
2015.11.20		
Date 日期	*Name Approved /批准人的名字*	*Signature Approved /批准人签字*

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
I.	**General Requirements** **通 用 要 求**				
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended 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. Usability and Users to be addressed. 器械的生产和设计必须保证：按照其预定用途和条件使用，器械不会损害临床条件、或患者安全、或操作者或其他人员的安全和健康；假设与器械预期用途相关的任何风险，与之给患者带来的益处相比，并与健康安全的保护程度相一致，则是可接受的。 This shall include: 1. reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and 2. consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 应包括： 3. 尽可能地降低由于器械的人体工学特征和器械预期使用的环境（为患者安全设计的）的错误使用而产生的风	A	EN ISO14971:2012 EN 1618:1997 EN ISO 10993-1:2009 EN ISO 10993-5:2009 ISO 10993-10:2010	Risk analysis report (SHENGBOCE2-05) Biocompatibility test report (SHENGBOCE2-APPEDIX 2)	Quality Dept.

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	险， 和 4. 考虑技术知识、经验、教育和培训，预期用户（为非专业人员、专业人员、伤残人员或其他人）的医疗和身体条件。				
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: 10 eliminate or reduce risks as far as possible (inherently safe design and construction), 11 where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, ▪ Inform users of the residual risks due to any shortcomings of the protection measures adopted. 制造商采用的器械结构和设计方案，必须考虑在当前工艺技术条件下遵守安全原则。 在选择最合适方案时，制造商应按照以下顺序遵守原则： 12 尽可能地降低或避免风险 （固有的安全设计和结构） 13 对无法避免的风险，如适用，采取适当的防护措施，包括必要的报警。 14 告知用户由于所提供防护措施的缺陷而带来的残	A	EN ISO14971:2012 EN 1618:1997 EN ISO 10993-1:2009 EN ISO 10993-5:2009 ISO 10993-10:2010	Risk analysis report (SHENGBOCE2-05) Biocompatibility test report (SHENGBOCE2-APPEDIX 2)	Quality Dept.

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	留风险。				
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. 器械最后必须取得制造商期望获得的功能。器械设计、制造和包装应与第 1 条(2)(a)制造商所规定的一项或多项功能相适应。	A	EN ISO14971:2012 EN 1618:1997 EN ISO 10993-1:2009 EN ISO 10993-5:200 ISO 10993-10:2010	Risk analysis report (SHENGBOCE2-05) Biocompatibility test report (SHENGBOCE2-APPEDIX 2)	Quality Dept.
4.	The characteristics and performances referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. 在制造商确定的器械使用寿命期内，在正常使用可能出现的压力下，第 1，2，3 款指的各项特征和性能应不能影响临床条件、危害患者或其它人员的安全。	A	MEDDEV. 2.7.1:Rev.3 EN ISO14971:2012	Clinical Data (SHENGBOCE2-12) Risk analysis report (SHENGBOCE2-05)	Quality Dept.
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. 器械设计、生产和包装应当保证器械的特征和性能在运输和储存过程中，只要遵守制造商提供的有关说明和信息，就不会受到重大影响。	A	EN ISO 15223-1:2012 EN ISO 11607-1:2009 EN ISO 11607-2:2006 EN ISO14971:2012	Label (SHENGBOCE2-07) Packaging Validation Report Package Test Report	Quality Dept.

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6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended. 副作用的大小同器械的预期性能相比，是可接受的风险。	A	MEDDEV. 2.7.1:Rev.3 EN ISO14971:2012	Clinical Data (SHENGBOCE2-12) Risk analysis report (SHENGBOCE2-05)	Quality Dept.
6a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X. 证明符合基本要求必须包括按照附录 X 的临床评估	A	MEDDEV. 2.7.1:Rev.3	Clinical Data (SHENGBOCE2-12)	Quality Dept.
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION** **设计和结构的要求**				
7.	Chemical, physical and biological properties 化学、物理和生物特征				
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on the "General requirements". Particular attention must be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. • Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand. 器械的设计和生产必须保证达到本附录第I 部分的通用要求，另外应特别注意： • 合理选择原料，特别是易燃物质和有毒物质的选择； • 从器械预定功能出发考虑所选材料同人体生物组织、细	A	EN ISO14971:2012 EN 1618:1997 EN ISO 10993-1:2009 EN ISO 10993-5:2009 ISO 10993-10:2010	Risk analysis report (SHENGBOCE2-05) Biocompatibility test report (SHENGBOCE2-APPEDIX 2)	Quality Dept.

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	胞和体液的相容性。 • 如适用，事先已确认有效的生物物理学或模型研究的结果				
7.2	The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure. 器械的设计、制造和包装应当保证器械在运输、储存和使用过程中的污染和残留物对人体危害最低，应特别注意观察暴露于器械下的人体组织及其时间和频率。	A	EN ISO 15223-1:2012 EN ISO 11607-1:2009 EN ISO 11607-2:2006 EN ISO14971:2012	Label (SHENGBOCE2-07) Packaging Validation Report Package Test Report	Quality Dept.
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use. 器械设计和生产必须保证在正常使用和常规过程中接触其它材料、物质和气体不会影响其安全使用；如果器械需要加载其它药品，器械的设计和生产必须保证同该药品相兼容，必须考虑法规对该药品的规定和限制，保证器械达到预定功能。	A	EN ISO14971:2012 EN ISO 10993-1:2009 EN ISO 10993-5:2009 ISO 10993-10:2010	Risk analysis report (SHENGBOCE2-05) Biocompatibility test report (SHENGBOCE2-APPEDIX 2)	
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the	N.A			

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	body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. 如果某种器械含有某种物质作为其组成部分，而且该物质单独使用时可被认为是 2001/83EC 第 1 条含义内的药品，并且它能够帮助该器械对人体产生辅助作用，这种物质的安全性、质量和有效性必须通过 2001/83/EC 指令附录I 涉及的适用方法进行类推来确认。 For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004[1] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 对于第一段提到的物质，在考虑到该器械的预期用途时确认了该物质作为医疗器械一部分的有效性之后，公告机构应按Regulation (EC) No 726/2004[1] 法规，就该物质的质量和安全性包括该物质与器械整合的临床受益/风险特性，向成员国指定的一个主管当局或欧洲药品评价署				

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.

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	（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或 EMEA 应考虑公告机构认定的关于该物质与器械整合有效性的生产过程和数据。 Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing this opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 如果某种器械含有人血制品作为其组成部分，在确认了该血制品作为医疗器械一部分的有效性，并考虑到该器械的预期用途的基础上，公告机构应就该制品的质量和安全性包括该制品与器械整合的临床受益/风险特性，向欧洲药品评价署（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或EMEA应考虑公告机构认定的关于该物质与器械整合有效性的生产过程和数据。 Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of				

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	the addition of the substance in the medical device. 如果器械整合的辅助物质发生了变更，特别是关系到其生产过程，公告机构应被通知并向相关的药品主管当局（也就是最初的咨询机构）咨询，以确认辅助物质的质量和安全性得以维持。主管当局应考虑公告机构认定的关于该物质与器械整合有效性的数据，以确保这种变更对已经建立的医疗器械中的增加物质的临床受益/风险特性没有负面影响。 When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. 当相关的药品主管当局（也就是最初的咨询机构）得到关于辅助物质对已经建立的医疗器械中的增加物质的临床受益/风险特性有影响的信息后，应向公告机构提出建议，该信息是否影响已经建立的医疗器械中增加物质的临床受益/风险特性。公告机构应考虑到更新的科学意见，以重新考虑对符合性评价程序的评价。				
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC[2] of 27 June	N.A			

[2] Internal note: replaced by (EC) 1272/2008

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	1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[3]. 器械的设计和制造，必须将源自器械的物质泄漏的风险降至最低。应当特别注意按1967年6月27日成员国法律中67/548/EEC[2]委员会指令附录I界定的致癌物、诱基因突变物和生殖毒性物质相关的危险物质[3]对分类、包装和标签的法律法规，行政条款的符合。 If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC[2], these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. 如果器械的一部分（或器械本身）预期用于对身体给药或除药、体液或其它物质，或预期用于运输或存储这些体液或物质，包含有按67/548/EEC[2]指令附录I界定的1类或2类致癌物、诱基因突变物或生殖毒性物质的邻苯二甲酸盐，该器械必须在自身和/或每台的包装上作出标识，及适当时在器械的销售包装上作出含有邻苯二甲酸盐的标识。 If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the				

[3] OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

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	instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. 如果器械的预期用途包括对儿童、孕妇或哺乳期妇女的治疗，制造商必须在技术文档和使用说明书中提供具体的使用这些物质的理由，及关于对这些患者群的残留风险，如适用，和合适的防范措施等信息，以符合基本要求，特别是本条的要求。				
7.6	The devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. 考虑到器械和预期使用的环境，器械的设计和生产必须保证，最大限度地降低由于异物进入而造成危害的可能性。	A	EN ISO14971:2012	Risk analysis report (SHENGBOCE2-05)	Quality Dept.
8.	Infection and microbial contamination 感染和微生物污染				
8.1	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use. 器械设计和制造工艺应当保证最大限度地降低甚至避免患者、使用者和其他人员之间交叉感染的可能性；器械应当操作简单，必要时，减少患者对器械、器械对患者的接触污染。	A	EN ISO14971:2012 EN ISO 15223-1:2012 EN 1041:2008 EN ISO 14644-1:1999 EN ISO 14644-2:2000 EN ISO 14698-1:2003 EN ISO 14698-2:2003	Risk analysis report (SHENGBOCE2-05) Label (SHENGBOCE2-07) Instruction for use (SHENGBOCE2-08) Environment control	Quality Dept.
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.	N.A			

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	动物源组织必须从对按组织的预期用途被进行控制和监管的动物中取得。 Notified Bodies shall retain information on the geographical origin of the animals. 公告机构应保留动物的原生地的信息。 Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. 对动物组织、细胞和其它动物源物质的加工、贮存、检验和处理，必须提供最可靠的安全保障。特别是病毒和其它传染物质的安全，在生产过程中有采取有效的消除方法或进行病毒灭活。				
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. 无菌器械的设计、生产和包装应采用一次性使用包装方式，并且在一定工作程序下保证器械上市时处于无菌状态，在贮藏、运输条件下只要包装不破损或开封，能够保持无菌状态。	A	EN ISO 11607-1:2009 EN ISO 11607-2:2006 EN ISO11135-1:2007	Packing Verification Sterilization Verification	Quality Dept.
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method. 无菌器械必须通过专门、有效的方法进行生产和灭菌。	A	EN ISO11135-1:2007	Sterilization Verification	Quality Dept.

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8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions. 需要灭菌的器械在专门控制的环境下生产。	A	EN ISO 14644-1:1999 EN ISO 14644-2:2000 EN ISO 14698-1:2003 EN ISO 14698-2:2003	Production Environment Control	
8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer. 非灭菌器械的包装系统，应当保证产品达到规定的清洁度。如果器械需要在使用前灭菌，应减少器械灭菌前微生物污染的可能性。包装系统必须适合于制造商所指定的灭菌方式。	N.A			
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. 相同或相似的产品销售时处于无菌状态还是非无菌状态，器械必须具有不同的包装和/或标签。	N.A			
9.	Construction and environmental properties 结构和环境特征				
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction for use.	N.A			

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	器械如果需要同其它器械或设备配合在一起使用，整个系统应保证安全，包括联接系统必须安全，不得改变器械的预定功能。必须在使用说明或标签上注明使用限制。				
9.2	Devices must be designed and manufactured in such a way as to remove or minimise as far as possible: 器械的设计和生产必须尽可能降低或避免： • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features, 由于器械物理性能特性，如体积压力比、外观尺寸、人体工学，对人体造成伤害的可能性。 • risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure, and acceleration, 在合理的环境条件下，如电磁场、外部电子干扰，静电放射、大气压、气温以及压力变化和加速度等条件下，对人体造成伤害的可能性。 • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, 在治疗或试用时，同其它器械相互干扰对人体造成伤害的可能性。 • risks arising where maintenance or calibration are not possible (as with implants) from ageing of the materials used or loss of accuracy of any measuring or control mechanism.	A	EN ISO 14971:2012	Risk analysis report (SHENGBOCE2-05)	

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	如果无法维修或矫正(如植入人体后),由于材料老化、测试或控制机能精度不够，对人体造成伤害的可能性。				
9.3	Devices must 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 must be paid to devices whose intended use includes exposure to flammable substances which could cause combustion. 器械的设计和生产必须保证，在正常使用情况下或单一故障的情况下，器械不至于起火或爆炸。对在暴露于易燃物质环境下使用的器械必须给予特别注意。	N.A			
10.	Devices with a measuring function 具有测量功能的器械				
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer. 检测器械的设计和生产必须保证足够的精度和稳定性、符合器械预定功能的要求。制造商必须注明其精度范围。	N.A			
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device. 必须根据器械的预定功能，按照人体工学的原理设计器械的度量、监控和显示刻度。	N.A			

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10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC[4]. 测量器械必须使用法定度量单位，符合理事会法令 80/181/EEC[4] 的规定。	N.A			
11.	Protection against radiation 辐射保护				
11.1 11.1.1	*General* *原则* Devices shall be designed and manufactured such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. 器械的设计和生产必须保证在达到预定功能的情况下，尽量减少对患者、使用者和其它人员的辐射，但不限制为治疗和诊断疾病使用规定合理的剂量。	N.A			
11.2 11.2.1	*Intended radiation* *预期的辐射* Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. 用于特定医疗目的，有的器械辐射危害人体健康的射线，	N.A			

[4] OJ No L 39, 15. 2. 1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7. 12. 1989, p. 28).

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	这种器械对患者的治疗作用同射线相比可以为人们所接受。器械辐射剂量必须能够控制，(设计和生产时)必须考虑其可变参数的可重复性和容差。				
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions. 设计器械发射危害性射线，不论射线是否可见，都应根据实际需要安装可见的显示装置和发声的报警装置，指示射线的发射状态。	N.A			
11.3 11.3.1	*Unintended radiation* *非预期的辐射* 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 be reduced as far as possible. 器械的设计和制造应当保证，尽量减少对患者，使用者以及其它人员产生非预期的意外辐射。	N.A			
11.4 11.4.1	*Instructions* *使用说明* The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. 放射性医疗器械应详细说明辐射特性、对患者和操作者的保护措施、任何防止操作错误以及消除由于安装器械带来的潜在危险。	N.A			
11.5	*Ionising radiation*	N.A			

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11.5.1	*电离辐射* Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended uses. 电离辐射器械的设计和生产必须保证，可以改变和控制电离辐射的数量，形状和质量，满足预定使用功能的实际需要。				
11.5.2	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user. 诊断用电离辐射器械的设计和生产必须保证，在获得清晰图象、提高输出质量、达到预定医疗目的的情况下，尽量减少对患者和使用者的照射。	N.A			
11.5.3	Devices emitting ionising radiation intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation. 治疗用电离辐射器械的设计和生产必须保证，能够有效地监控照射剂量、离子束类型、能量大小以及离子束的质量。	N.A			
12.	Requirements for medical devices connected to or equipped with an energy source 连接或配备能源的医疗器械的要求				
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their	N.A			

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	intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks 带有可编程系统的器械设计应保证其可重复性、可靠性、满足预定功能的需要。应当采取必要措施、减少因出现单一故障状态而造成危害的可能性。				
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. 对于合并软件使用的或本身是医疗软件的器械，软件必须考虑研发生命周期、风险管理、确认和验证的原则，按照当前的技术发展水平进行确认。	N.A			
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply. 对维系患者安全的器械，内部供电时，应配有电源指示装置，表明电源的供电状况。	N.A			
12.3	Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure. 对维系患者安全的器械，外部供电时，应增加报警装置，报告电源中断。	N.A			
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. 监测患者临床数据的器械，必须配置相应的报警系统，提醒操作者可能导致患者死亡或病情严重恶化的情况。	N.A			

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
12.5	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment. 器械的设计和生产必须保证，尽量减少由于产生电磁场，影响其它器械或设备的操作使用造成的危害。	N.A			
12.6	*Protection against electrical risks* *防止触电危险.* Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly. 假定器械安装正确，器械的设计和生产必须尽量减少在正常使用和出现单一故障时，意外电击的危险。	N.A			
12.7 12.7.1	*Protection against mechanical and thermal risks* *高温和机械防护* Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts. 器械的设计和生产必须保证患者、使用者不受机械部件造成的损伤，如阻力部件、稳定性部件和移动性部件造成的损伤。	N.A			
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制振动(特别是振动源)的措施，最大限度地降低器械振动	N.A			

Checklist according to annex I of the Medical Device Directive (MDD) 按 医 疗 器 械 指 令 （MDD） 附 录 一 的 基 本 要 求 检 查 表		A/ NA 适用/ 不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	造成的危害，除非所发出的振动是特定功能的需要。				
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制噪音(特别是噪音源)的措施，最大限度地降低器械噪音造成的危害，除非所发出的声音是特定功能的需要。	N.A			
12.7.4	The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimise all possible risks. 操作者接触的电源、气动、气压端口和连接件，设计和生产必须考虑减少各种危险的可能性。	N.A			
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use. 在正常使用的情况下，人体可接触到的器械部件及其周围，温度不得过高，以免造成危险；但不包括专门用于提供热量或必须达到一定温度的部件和区域。	N.A			
12.8 12.8.1	Protection against the risks posed to the patient by energy supplies or substances 防止能源提供和物资供应造成对患者的危险 Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	N.A			

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	为患者提供能源或物质的器械设计和生产必须保证，器械可以控制流量，保证足够的精度，保证患者和使用者的安全。				
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. 器械必须配有专门装置，防止出现流量波动给患者带来危险，或出现问题时报警。 Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source. 器械必须配备适当的装置尽量避免能量和/或物质意外增加到危险的程度。	N.A			
12.9	The function of the controls and indicators must be clearly specified on the devices. 指示器和控制按钮、手柄等必须在器械上予以注明。 Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient. 如果器械通过可视系统提供操作说明，通过可视系统显示和修改各种参数，可视系统显示的信息必须能为操作者所理解，必要时患者也应看得懂。	N.A			
13.	Information supplied by the manufacturer 制造商提供的信息				
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. 考虑到对于潜在使用者的培训和认知，以及识别制造商，	A	EN ISO 15223-1:2012 EN1041:2008	Label (SHENGBOCE2-07) Instruction for use (SHENGBOCE2-08)	

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	每个器械必须附带所需信息，以安全正确使用。 This information comprises the details on the label and the data in the instructions for use. 这些信息器械应在标签或使用说明书具体说明。 As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. 根据实际需要，在器械上、在每个器械的包装上或在销售包装上都应注明安全使用所需要的操作信息。如果不可能对每个器械单独包装，则应随每一个器械或一定数量的器械提供活页说明。 Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions. 每个器械的包装中应附带使用说明，但I 类或IIa 类器械，如果不需要使用说明书也可以安全使用，可以除外。				
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device. 根据需要应通过使用标志说明操作信息。器械使用的标志或识别颜色应符合欧洲共同体协调标准。如果没有统一标准，标志和识别颜色的含义必须在器械附带的资料中说明。	A	EN ISO 15223-1:2012 EN1041:2008	Label (SHENGBOCE2-07) Instruction for use (SHENGBOCE2-08)	

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
13.3	The label must bear the following particulars: 器械标签必须具有下列内容：				
	a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community; (a)制造商的名称或商品名以及地址。为了在欧洲共同体内销售，如果制造商在欧共体内没有注册场地，则进口的器械标签、或外包装或使用说明书中应另外注明授权代表的名称和地址。	A	EN ISO 15223-1:2012	Label (SHENGBOCE2-07)	
	b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (b) 使用者识别器械和了解包装内容必需的信息；	A	EN ISO 15223-1:2012	Label (SHENGBOCE2-07)	
	c) where appropriate, the word "STERILE"; (c)必要时，注明“已灭菌”字样；	A	EN ISO 15223-1:2012	Label (SHENGBOCE2-07)	
	d) where appropriate, the batch code, preceded by the word "LOT", or the serial number; (d)必要时，注明批号或系列号，批号以“LOT”打头；	A	EN ISO 15223-1:2012	Label (SHENGBOCE2-07)	
	e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; e) 必要时，注明器械安全使用的期限，以年和月表示。	A	EN ISO 15223-1:2012	Label (SHENGBOCE2-07)	

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; f) 必要时，注明器械属于一次性使用。制造商的一次性使用标识必须在欧共体内统一。	A	EN ISO 15223-1:2012	Label (SHENGBOCE2-07)	
	g) if the device is custom made, the words "custom made device"; g) 如果属于定作器械，注明"定制器械"字样。	N.A			
	h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations"; h) 如果属于临床试用的器械，注明"专门用于临床研究"字样	N.A			
	i) any special storage and/or handling conditions; i) 特殊储存条件和/或管理要求；	A	EN ISO 15223-1:2012	Label (SHENGBOCE2-07)	
	j) any special operating instructions; j) 特殊操作说明；	N.A			
	k) any warnings and/or precautions to take;		EN ISO 15223-1:2012	Label	

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	k) 任何警告和/或注意事项 l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number; l) 有源器械的生产年份，如不为(e)项所含，则也可以包含在批号或系列号内。 m) where applicable, method of sterilisation. m) 如适用，注明灭菌方法。 n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative." n) 若器械涉及第一章 1(4a)条款，注明器械含有人血制品	A N.A A N.A	EN ISO 15223-1:2012	(SHENGBOCE2-07) Label (SHENGBOCE2-07)	
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. 如果器械的预定功能对操作者来说不是显而易见的，制造商在标签和说明书上应当加以清楚阐述。	N.A			
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. 当合理和可行时，器械和可拆卸部件必须加以识别，就批量而言，可以采取各种有效方法对器械和拆卸部件带来的潜在风险加以识别。	N.A			
13.6	Where appropriate, the instructions for use must contain the following particulars:				

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
若适用，使用说明书必须包含以下说明： a) the details referred to in 13.3, with the exception of d) and e) a) 本附录第 13.3 款所指除(d)和(e)项以外的各项内容；	A	EN1041:2008	Instruction for use (SHENGBOCE2-08)	
b) the performances referred to in section 3 and any undesirable side effects; b) 本附录第 3 款所指使用性能及其可能带来的副作用。	N.A			
c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; c) 如果必须同其它器械或设备一同安装或连接使用，应当详细说明配合使用的器械或设备的特性，以便取得预期的功能。	A	EN1041:2008	Instruction for use (SHENGBOCE2-08)	
d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; d) 鉴别器械是否正确安装所必要的技术信息，保证准确、安全使用；以及维护和校准器械所必须的技术指标或频率，保证器械长期准确、安全使用的所有信息。	N.A			

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
e) where appropriate, information to avoid certain risks in connection with implantation of the device; e) 对植入人体的器械，如果需要，应加以特别说明，避免出现植入人体器械特有的危险。	N.A			
f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; f) 在进行特定检查和治疗的过程中，器械产生相互干扰的危险性说明。	N.A			
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation g) 说明灭菌包装损坏后，器械如何进行处理；如果可能，说明重新灭菌的有效方法。	A	EN1041:2008	Instruction for use (SHENGBOCE2-08)	
h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of he device to be resterilized, and any restriction on the number if reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I). If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could	N.A			

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; h) 可重复使用的器械，应说明准确使用的方法，包括清洁、消毒、包装以及，如适用，对需要再次灭菌器械进行灭菌的方法，重复使用的次数限制。 如果器械预期要在使用前灭菌，按照清洁和灭菌的使用说明书要求正确执行，器械仍符合第 1 部分的要求。如果器械附带了一次性使用的标识，制造商已知的由于已知特性以及技术因素使器械重复使用带来风险的信息。如果按 13.1 部分的规定不需要使用说明书，则信息必须应使用者要求而提供。 i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.) i) 器械使用前如何进行处理，如灭菌、最后组装等； j) in the case of devices emitting radiation for medical purpose, details of the nature, type intensity and distribution of this radiation j) 利用放射线治疗的器械，必须说明放射线的特性、类型、密度和分布 The instruction for use must also include details, allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: 使用说明书必须另外说明，医护人员如何向消患者说明禁忌症和注意事项，具体包括： k) precautions to be taken in the event of changes in		N.A A N.A	EN1041:2008	Instruction for use (SHENGBOCE2-08)	

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Location (文件存放部门)
	the performance of the device; k)器械性能发生变化时的注意事项；	N.A			
	l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.; l) 在可预见的使用环境下，在电磁场、外界电流、静电放射、大气压以及大气压发生变化、加速度、热力源等作用下，应当采取的注意事项	N.A			
	m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; m) 应当详细说明器械加载的药品或其它物质的性能，包括其选择物质的限制范围；	N.A			
	n) precautions to be taken against any special, unusual risks related to the disposal of the device; n)处置器械时防止出现特别、意外风险的注意事项。	N.A			
	o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; o)说明第 7.4 款所指同器械结合一体使用的药物或人血制品；	N.A			
	p) degree of accuracy claimed for devices with a measuring function. p)具有测试功能的器械应说明声称的精度。	N.A			

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	q) date of issue or the latest revision of the instructions for use. q) 使用说明书最新版本或修订日期	A	EN1041:2008	Instruction for use (SHENGBOCE2-08)	

Risk Analysis Report

1. Summary

This document is a risk analysis for the Disposable vaginal speculum. All hazards and each potential reason causing the relevant hazard have been judged in this document. This document also estimates the degree of harm caused by all kinds of hazards and the probability of occurrence of the hazards. If there are acceptable ways to reduce the risk, description have been made and the remaining risk level after making the ways has been estimated.
Result: By means of considerable ways, all risk, which may cause hazard, are reduced to an acceptable level, and the total number of all kinds of hazards is reduced to an acceptable level. Risk is proportional to usability.

2. Reference document

1. MDD 93/42/EEC
2. EN ISO14971:2012

3. Description of Disposable vaginal speculum

The Disposable vaginal speculum is used for gynecological examination.

3.1 Intended Use

The Disposable vaginal speculum is used for gynecological examination.

4. Responsible group

The group of risk analysis consists of the following person:

Name	Title	Responsibility	Authority
	Quality manager	Risk management for R&D phase	Review, approve the risk management plan and risk management report.
	Production manager	Risk management for product realization phase	Review and implement the risk management plan
	Quality manager	Risk management for product realization phase	Review and implement the risk management plan
	Sales manager	Risk management for post-marketing	Review and implement the risk management

		surveillance phase	plan
	Quality manager	Risk management for clinical use phase	Review and implement the risk management plan
	Technician	Prepare the risk analysis report	/

5. Determination list of relative risk characteristics

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

5.1. What is the intended use and how is the medical device to be used?
Intended use:

The Disposable vaginal speculum is used for gynecological examination.

5.2 Is the medical device intended to be implanted?

No.

5.3 Is the medical device intended to be in contact with the patient or other persons?

The product contact with patients and users in short terms.

5.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?

Medical PC ,PS and PE.

5.5 Is energy delivered to or extracted from the patient?

No

5.6 Are substances delivered to or extracted from the patient?

No.

5.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or tansplatation?

No.

5.8 Is the medical device supplied sterile or intended to be sterilized by the user or are other microbiological controls applicable ?

Sterile product.

5.9 Is the medical device intended to be routinely cleaned or disinfected by the user?

No. For single-use.

5.10 Is the medical device intended to modify the patient environment?

No.

5.11 Are measurements taken?

No.

5.12 Is the medical device interpretative?

No.

5.13 Is the medical device intended for use in conjunction with other medical devices, machines or medical technologies?

No.

5.14 Are there unwanted output of energy or substances?

Potentially taking articles such as metal, dust particles, foreign substrates, microorganism, hair and insect in production process.

5.15 Is the medical device susceptible to environmental influences?

The package validation was performed, the product must be controlled with sterile. Affect the cleanliness of product if the environment is not clear.

5.16 Does the medical device influence the environment?

Potentially contaminate the environment if product has not been destoried after use.

5.17 Are there essential consumables or accessories associated with the medical device?

No.

5.18 Is maintenance or calibration necessary?

No

5.19 Does the medical device contain software?

No.

5.20 Does the medical device have a restricted shel-life?

5 years shelf-life.

5.21 Are there any delayed or long term use effects?

No.

5.22 To what mechanical forces will the medical device be subjected?

No.

5.23 What determine the lifetime of the medical device?

Sterilization expiration and materials aging determind products useful time.

5.24 Is the medical device intended for single use?

For single-use only.

5.25 Is safe decommissioning or disposal of the medical device necessary?

Disposal by doctors.

5.26 Does installation or use of the medical device require special training or special skills?

The Disposable vaginal speculum should be operated by trained doctors.

5.27 How will information for safe use be provided?

Cautions and Instruction for use should be provided to user directly.

5.28 Will new manufacturing processes need to be established or introduced?

No.

5.29 Is successful application of the medical device critically dependent on human factors such as the user interface?

5.29.1 Can the user interface design features contribute to use error?

No.

5.29.2 Is the medical device used in an environment where distractions can cause use error?

No.

5.29.3 Does the medical device have connecting parts or accessories?

No.

5.29.4 Does the medical device have a control interface?

No.

5.29.5 Does the medical device display information?

No.

5.29.6 Is the medical device controlled by a menu?

No.

5.29.7 Will the medical device be used by persons with special needs?

No.

5.29.8 Can the user interface be used to initiate user actions?

No.

5.30 Does the medical device use an alarm system?

No.

5.31 In what way(s) might the medical device be deliberately misused?

No.

5.32 Does the medical device hold data critical to patient care?

No.

5.33 Is the medical device intended to be mobile or portable?

No.

5.34 Does the use of the medical device depend on essential performance?

No.

6. Hazards determination

6.1 Judgement of possible hazard

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

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

Energy hazards and contributory factors	**Reasons**
electricity	**----**

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

biological hazards and contributory factors	**Reasons**
bio-contamination	1. The bio-burden on the product exceeds the limit; 2. Imperfect sterilization cause the product micro-polluted; 3. Pollution in packing, storage and transport.
bio-incompatibility	Incompatibility between raw material and human body structure.
Incorrect output	Contains foreign substance or hair
incorrect formulation (chemical composition)	----
toxicity	Material is poisonous; packing material is poisonous
allergenicity	----
mutagenicity	----
teratogenicity	----
oncogenicity	----
carcinogenicity	----
re-and/or cross-infection	----
pyrogenicity	----
inability to maintain hygienic safety	Contamination because the product hasn't been destroyed immediately after use.
degradation	The material is degraded because of heat, light and other reasons.

Environmental hazards and contributory factors	**Reasons**
electromagnetic fields	----
susceptibility to electromagnetic interference	----
emissions of electromagnetic interference	----

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

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

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

devices	
sharp edges or points	----

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

Hazards arising from functional failure, maintenance and ageing and contributory factors	**Reasons**
Erroneous data transfer	----
lack of, or inadequate specification for maintenance including inadequate specification of post-maintenance functional checks	----
inadequate maintenance	Protection process does not comply with regulations

lack of adequate determination of the end of life of the medical device	No specific period of validity or incorrect stipulation of service life
loss of electrical/mechanical integrity	Packing damage, product damage
inadequate packaging (contamination and/or deterioration of the medical device)	The seal of packaging is bad.
re-use and/or improper re-use	Reuse of product for single use
deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	----

6.2. Determination on known and foreseeable hazards

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

H1. Microorganism infection: bacterial infection due to halfway sterile or damaged packing, it may lead bacterial infection.

H2. Biocompatibility (allergic reaction): incompatiblity of material itself or packing material with human body structure.

H3. Toxicity: material or packing material itself is poisonous.

H4. Foreign substances: foreign substance or hair contains in product or packing material, may enter into human body, and bring hazard to human body (e.g. inflammation).

H5. Other baneful chemistry: heavy metal, acidity-alkali degree and oxide exceed standard, symptoms such as vomit, toxicosis will apper on the patient, also reduce medicine effect, and destroy balance of body liquid, then influence therapeutic effect.

H6. Remnant EOG exceeds the standard, cause poor immunity of the patients, it may cause cancer.

H7. Incorrect use or improper guidance led by inadequate or error of label or attention iterms.

H8. Improper use by non-medical care personal.

H9. Patient infection led by re-use of the disposable product.

H10. Improper operation of medical personnel or product that already exceeded expiry date to be used by the medical care personnel led by unclearly printing on the package.

H11. The syringe have burr.

H12. The syringe is leaked.

H13. Acid or alkalinity.

H14 Bad bending resistance, tensile properties, and air leakage resistance.

H15 Clamp broken

H16 Production lot number can not be traced after sale

7. Risk control

7.1 All measures

M1. Strictly control sterile process.

M2. Carry out effective verification on sterile performances.

M3. Carry out effective verification on packing performances.

M4. Select raw material of medical class with appropriate hardness and select packaging for medical use.

M5.Strictly control environment during production process, set up purifying workshop environment control procedure, workshop staffs detect clump count regularly, detect product intial contamination bacteria regularly, product to be sterile effectively, all key factors contact with product must under control.

M6. Product must be used immediatly after the package is open.

M7. Production process and environment must be strictly under control, set up stipulations for procedure, make sure that no foreign substances may enter into purifying workshop, and also staff's work cloth can effectively prevent falling down of foreign substances, such as hair and fiber, etc.

M8. Raw material suppliers must under strict control, strengthen test on raw material purchasing.

M9. Strengthen control resolution room, add compulsive resolution devices.

M10. Use dialytic paper packaging.

M11. To evaluate the label and IFU of the product, ensuring its compliance with EN 980 and EN 1041 requirements.

M12. Release of the label must be under strict control.

M14. Control of the key process.

M15. Improvement of self-check and sampling check.

M16. Training of the operator.

M17. Supplier evaluation.

M18. Inspection according to the sampling plan.

M19. Control of material, inspection all kinds of material.

M20. Control the accessory ingredient.

M21. Final inspection of chemical performance passed.

M22. In-process inspection of process parameters.

M23. Strictly conduct identification and traceability in production and after sale process.

7.2 Risk control form

7.2.1 Step1: Determination on known and foreseeable hazards

The hazard will be marked with “H……” in risk control form. (see the risk analysis report)

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

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

7.2.1.1 Estimation on severity level of each hazard

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

Item	Severity level	Description	Sample
1	Neglectable	Have almost no or no potential possibility of harm	Temporary sick
2	Slight	Much harm occurred	Damage of blood vessel and muscle
3	Dangerous	Serious hurt or even dead	Bacteria contamination, exanimation or dead
4	Catastrophic	Many people were seriously hurt or dead	Fatal virus proliferate at large scale, many people were infected

7.2.1.2 Judgment of potential causes of each hazard

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

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

7.2.1.3 Estimation on probability of occurrence of each cause

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

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

Such estimation carried out by relative personnel can be divided into following 6 categories:

No	Category	Description
1	Almost impossible	Never occurred
2	Much less	The typical condition is: according to feedback of the customer, the occur rate of foreign substance is less than millionth
3	Seldom	The typical condition is: package of 1 in 1000 cannot be tear open
4	Unmeant	The typical condition is: 1 was found in 100 products
5	Likely	The typical condition is: often found during use of the product
6	Frequent	The typical condition is: occurred in each use

Estimation on probability of occurrence probability of the hazard

If possible, the probability of occurrence of the hazard can be divided into following 6 levels:

Level	Probability of occurrence
6 Frequent	≥1
5 Much possible	$1—10^{-1}$
4 Seldom	$10^{-1}—10^{-2}$
3 Much less	$10^{-2}—10^{-4}$
2 Extremely less	$10^{-4}—10^{-6}$
1 Almost no possible	$<10^{-6}$

7.2.2 Step2: Risk estimation (before taking control measures)

Two risk factors were concluded in first hazard/cause item: hazard severity level and occurrence probability, relative risk. Three “risk area” can be defined according to advise of EN ISO14971:2012.

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

7.2.3 Step3: Risk evaluation

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

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

U: Unacceptable risk

A: Insignificant risk

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

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

Risk control form see Appendix A.

8. Result of risk control

No relevant measures have been taken

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)					
Probable (P4)				1	
Occasional (P3)			7		
Remote (P2)			10		
Improbable (P1)					

Relevant measures have been taken

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)					
Probable (P4)					
Occasional (P3)					
Remote (P2)					
Improbable (P1)			17	1	

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

9. Conclusion

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

Potential Risk	Causes	Before taking control measures			Control measures	New risk	Residual risk		
		S	P	R			S	P	R
H1. Bacterial infection	C1. Bacteria contains in the product C1.1. Bacteria was bring in during production process. C1.2. Other organic substances was bring in during production process. C1.3. Sterile was not thoroughly.	3	3	U	M1. Strictly control sterile process. M2. Carry out effective verification on sterile performances. M3. Carry out effective verification on packing performances. M5.Strictly control environment during production process, set up purifying workshop environment control procedure, workshop staffs detect clump count regularly, detect product initial contamination bacteria regularly, product to be sterile effectively, all key factors contact with product must under control. M6. Product must be used immediatly after the package is open.	No	3	1	A
H2. Biocompatibility of the material	C2. Foreign substances contains in the product that is antipathic wiht human body. C2.1. The product is not medical class material. C2.2. Foreign substances was brought in during production process. C2.3. The packing material is not medical class	3	3	U	M4. Select raw material of medical class with appropriate hardness and select packaging for medical use. M7. Production process and environment must be strictly under control, set up stipulations for procedure, make sure that no foreign substances may enter into purifying workshop, and also staff's work cloth can effectively prevent falling down of foreign substances, such as hair and fiber, etc.	No	3	1	A
H3. Raw mateiral and packing material are poisonous	C3. Raw material and packing materials are not medical class	4	4	U	M4. Select raw material of medical class with appropriate hardness and select packaging for medical use.	No	4	1	A
H4. Foreign substances or hair contains in the product	C4.1. Foreign substances contains in packing but outside the product. C4.1.1. Brought in by purchased packing material C4.1.2. Brought in during production process	3	2	A	M7. Production process and environment must be strictly under control, set up stipulations for procedure, make sure that no foreign substances may enter into purifying workshop, and also staff's work cloth can effectively prevent falling down of foreign substances, such as hair and fiber, etc. M8. Raw material suppliers must under strict	No	3	1	A
	C4.2. Foreign substances contains in the product.	3	2	A		No	3	1	A

	C4.2.1. Brought in by purchased spare part C4.1.2. Brought in during production process				control, strengthen test on raw material purchasing.					
Potential Risk	**Causes**	**Before taking control measures**			**Control measures**	**New risk**	**Residual risk**			
		S	**P**	**R**			**S**	**P**	**R**	
H5. Exceeded heavy metal, acidity-alkall degree exceed standard, oxide exceed the standard	C5. The material is not medical class	3	2	A	M4. Select raw material of medical class with appropriate hardness and select packaging for medical use.	No	3	1	A	
H6. Remnant EOG exceed the standar	C6.1. Inadequate resolution C6.2. Packing material is not suitable for resolution of EOG	3	3	U	M9. Strengthen control resolution room, add compulsive resolution devices. M10. Use dialytic paper pakcing.	No	3	1	A	
H7. Misuse and incorrect instruction led by erroneous or extremely less information on the label	C7.1. The label was incorrectly designed	3	3	U	M11. To evaluate the label and IFU of the product, ensuring its compliance with EN 980 and EN 1041 requirements.	No	3	1	A	
	C7.2. The label was misused	3	3	U	M12. Release of the lables must be under strict control.	No	3	1	A	
H8. Misuse led by using of non-medical care personnel	C8.1. Used by non-medical care personnel for the patient	3	2	A	M11. To evaluate the label and IFU of the product, ensuring its compliance with EN 980 and EN 1041 requirements.	No	3	1	A	
	C8.2. Take for other use	3	2	A	M11. To evaluate the label and IFU of the product, ensuring its compliance with EN 980 and EN 1041 requirements.	No	3	1	A	
H9. Reuse of disposable product	C9. Incorrect operation of medical care personnel	3	2	A	M11. To evaluate the label and IFU of the product, ensuring its compliance with EN 980 and EN 1041 requirements.	No	3	1	A	
H10. Printing of the package is not clear	C10. Process contrl was neglected.	3	2	A	M13. Strengthen controls on production and testing procedures (such as 100% inspection).	No	3	1	A	
H11. The syringe have burr	C11.1. Injection parts defects C11.2. Mould has a problem C11.3. Process inspection lax	3	2	A	M9. Strengthen control resolution room, add compulsive resolution devices. M14. Control of the key process. M15. Improvement of self-check and sampling check. M17. Supplier evaluation.	No	3	1	A	

					M19. Control of material, inspection all kinds of material.				

Potential Risk	Causes	Before taking control measures			Control measures	New risk	Residual risk		
		S	P	R			S	P	R
H12. Leakage	C12. If the product is leaked, the product is failed.	3	2	A	M15. Improvement of self-check and sampling check. M17. Supplier evaluation. M19. Control of material, inspection all kinds of material. M20. Control the accessory ingredient.	No	3	1	A
H13. Acid or alkalinity	C13. If the nonconfromity of acid or alkalinity, may casue the patient hypersusceptibility, lack oxygen of organ, tetter, mulcosa edema.	3	2	A	M19. Control of material, inspection all kinds of material. M20. Control the accessory ingredient. M21. Final inspection of chemical performance passed.	No	3	1	A
H14 Bad bending resistance, tensile properties, and air leakage resistance.	C14. Wrong excluding process control.	3	3	U	M22. In-process inspection of process parameters.	No	3	1	A
H15 Clamp broken	C15. Wrong process validation control and daily routine process parameter control	3	3	U	M22. In-process inspection of process parameters.	No	3	1	A
H16 Production lot number can not be traced after sale	C19. Failure of product identification and traceability after-sale	3	3	U	M23. Strictly conduct identification and traceability in production and after sale process.	No	3	1	A

10. The information of production and post-production

Changshu Taining Medical Equipment. Co.,Ltd. designs and sales for medical device since the company found, the product is sold in China market and southeast of Asian for many years. From 2011, we distribute the Disposable vaginal speculum in China market, the product is high quality and recognized by customer and market share increase step by step. In order to share international market, we establish the quality system in accordance with MDD Directive.

Following is the History record of product and feedback:

Year	Sell to the countries and regions	Selling number (thousand)	Complaint number	Complaint content
2011	China, Russia	200	/	/
2012	China, EU	300	/	/
2013	China, Middle east, EU	440	/	/
2014	China, Middle east, EU	650	/	/
2015	China, Middle east, USA	400	/	/

From production process and post-production, following risk are recognized.

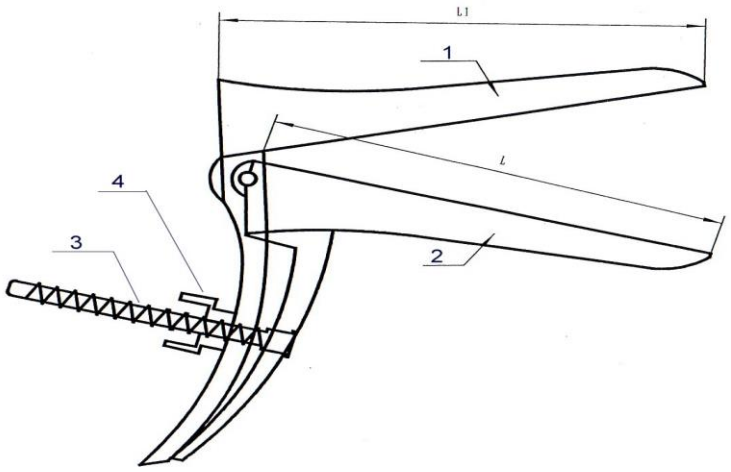
Date	New information of production and post-production	Conclusion of evaluating

General description of the product

1 Product configuration

The speculum is mainly made up of upper part, sub-part and handle. The configuration, model, specification and basic dimension can be seen in Fig 1 and Form 1.

Notice: Fig 1 shows the configuration of speculum. If other configurations can be according with the use requirements stipulated in this standard, they also can be used.



1. Upper part
2. Sub-part
3. Adjusting rod

Fig1：Configuration of single use vaginal speculum

2 Product specification

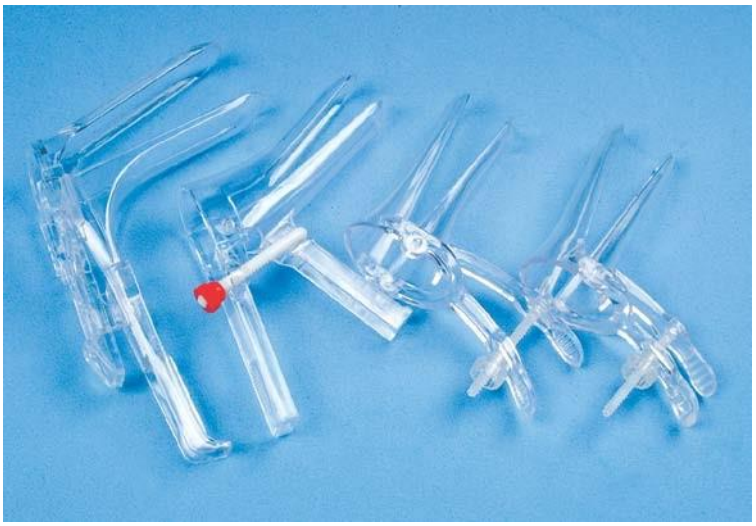
Form1 Model, Specification and basic dimension mm

Size	Basic Dimensions							
	L	L1	B	B1	B2	H	H1	H2
Large	118	118±2	45	36±1	36±1	115	10	10
Medium	100	100±2	38	28±1	28±1	110	7.5	8
Small	90	90±2	30	20±1	20±1	90	6.5	7

3 The selection of product material

Made from polyethylene according to YY 0114-1993 regulation.

4 Product shape



5 The packaging of product

5.1 The objective of packaging

Prevent the packed product from pollution so that the product's safety and effect can be guaranteed.

5.2 Packaging configuration and the selection of material

The packaging of product is dialytic paper + PE film or total PE film

5.3 Packaging technology

The main processes are made up of : mark printing, dialytic paper- total film molding , set in product, heat sealing etc and the products are packed manually.

5.4 Packaging effect

The sterilized initial packaging can guarantee that the product inside of the packaging can meet asepsis requirement in the valid period. See product sample observation report

6. Material and supplier

6.1 Nantong Kanghui plastic Ltd—— Supply polypropylene

6.2 Shanghai Xin shang hua macromolecule material Ltd.——Supply polystyrene

6.3 Shanghai Yate plastic Ltd—— Supply PC,PS and PE

6.4 Nantong Runfeng plastic Ltd.——PE film

Chapter 7. Labels and instruction for use

7.1 All important aspects of labelling

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

7.1.2 Product name, Model/size, specification, quantity

7.1.3 Batch code or the serial number

Symbol for "BATCH CODE"

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

Example of use of symbol for "BATCH CODE"

Where applicable, Symbol for "SERIAL NUMBER"

- The relative size of the symbol and the size of the serial number are not specified.
- Examples of use of symbol for "SERIAL NUMBER"

SN-ABC123

7.1.5 Expiry date

Symbol for "USE BY"

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

Examples of use of symbol for "USE BY"

7.1.6 An indication that the device is for single use

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

-Synonyms for "Do not reuse" are "single use", "Use only once".

7.1.7 Date of manufacture

- Symbol for "DATE OF MANUFACTURE"

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

- Example of use of symbol for "MANUFACTURER" combined with "DATE OF MANUFACTURE"

7.1.8 Catalogue number

- Symbol for "CATALOGUE NUMBER"

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

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

Examples of use of symbol for "CATALOGUE NUMBER"

REF ABC123

7.1.7 Caution

Symbol for "CAUTION"

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

7.1.10 Keep dry

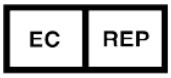
Symbol for “KEEP DRY”

7.1.11 CE mark

Drawings

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

7.1.12 symbol of Manufacturer 

7.1.13 symbol of EC-representative 

7.1.14 symbol of “STERILE” by EO:

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

7.2.1 Special requirements

7.2.1.1 The Modelface, symbol, size and location on label are not prescribed.

But the handwriting should be clear, obvious and durable.

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

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

7.2.2 Normative Reference

- MDD 93/42/EEC Annex I clauses 13 and annex V
- EN 980: 2008
- EN1041: 2008

Small Package of Disposable vaginal speculum

Disposable vaginal speculum

Model: S

150217

2015-X

Yuhuan County Shengbo Mould Manufacturing Co., Ltd.

CE 0123

2017-X

Middle Package

Front side:

Disposable vaginal speculum

Model: S

List of components:

Yuhuan County Shengbo Mould Manufacturing Co., Ltd.
Western of Chinese Sterile Medical Equipment Base,Qinggang Town,Yuhuan County,Zhejiang Province, China.
TEL: +86-576-86106537 FAX: +86-576-86106537

EC REP

KINGSMEAD SERVICE LIMITED
145-157 St John Street, London, EC1V 4PY (UK)
Tel/Fax: 044-20-32399738E-mail: office@kingsmead-service.com

Back side:

140217

2015-X

2017-X

CE 0123

Outside Package

Disposable vaginal speculum

Model: S

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EC REP
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LOT XX 2015-X 2017-X

STERILE EO CE 0123

Instruction for Use

[Product name]: Disposable vaginal speculum
[Types]: S, M, L
[Materials]: PS,PC and PE
[Intended use]: Vaginal Speculum is used for inspecting the vagina of clinic patient. Choose suitable specification Vaginal Speculum, push the closed Vaginal Speculum into vagina and to the place which need to be inspected, fix and screw down the bolt then inspect.
[Validity]: 5 years.
[Use method]:
First choose the compatible specification agaist the suffer.Then adjust vaginal speculum to the minimum level ,and then insert the front end into vagina and adjust the staff to proper level and then fix it .After checking ,return it to the minimum level ,finally draw it and discard it .
[Cautions]:
1. Vaginal speculum should be operated by the professional physician
2. For single use only，discard after use
3. Do not use if package is open or damaged.
4. If Product re-use, it may be result in re-infection or cross-infection.
5. Do not store in toxic, harmful, corroding condition.

[Storage and transportation]:
1. The device shall be stored at a relative humidity of less than 80%, the storage environment shall be kept non-corrosive gases, dry, avoiding sunlight, well-ventilated conditions, and clean.
2. The device shall be taken care during transportation and handling.

[Contact information]:

Yuhuan County Shengbo Mould Manufacturing Co., Ltd.
Western of Chinese Sterile Medical Equipment Base,Qinggang Town,Yuhuan County,Zhejiang Province, China.
TEL: +86-576-86106537 FAX: +86-576-86106537

The authorized representative of European Union:

KINGSMEAD SERVICE LIMITED
145-157 St John Street, London, EC1V 4PY (UK)
Tel/Fax: 044-20-32399738
E-mail: office@kingsmead-service.com

[Symbols]

CE 0123	CE certified by TUV SUD	LOT	Lot number
	Single use		Date of manufacture
STERILE EO	Sterilized by EO		Manufacturer
	Notice	EC REP	European union representative

Preclinical Assessment

1. Introduction

The CE products, Disposable vaginal speculum, must be made sure that it comply with the provisions of standards EN 1617:1997, ISO 8669-1:1998, ISO 8669-2:1996 and other relative standards before product manufacturing/clinical use, thus ensuring CE products in conformity with their intended uses, and also ensuring their safety and reliability.

All the following physical, chemical, biological and biocompatibility tests are conducted for purpose of preclinical assessment.

2. Type test

2.1 Physical test

See products test reports.

2.7 Sterility test

-Requirement: the sterility shall meet SAL=10^{-6}, when test according to EN ISO 11737-1:2006, EN ISO 11737-2:2009.

-Result: There are no bacteria or fungus growth

2.8 Residual EO

-Test method: according to annex B in ISO10993-7:2008

-Result: comply with the requirement.

2.9 Symbols & Labeling

-Test method: visual inspection

Result: Comply with EN980:2008 & EN1041:2008, EN 980:2008.

3. Biocompatibility

According to EN ISO 10993-1:2009+ AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, the Connecting tube with yankauer handle have been tested with regard to their bio-compatibility, an examination should be made to cytotoxicity, subcutaneous stimulation test, skin allergic reaction and Tests for local effects after implantation. Bio-compatibility test is followed:

3.1 Requirements:

1) Cytotoxicity test

a) It is determined in this test, by means of cell culturing technique, how the material and/or its diffusate would cause a cell dissolution(cell death) and a restraint on cell growth and propagation, and what other impacts it have, etc.

b) According to the above method, put the our product diffusate into L-929 cell fluid, and culture the cells for their growth and propagation, then evaluate the potential toxicity of the tested materials to cells.

2) Test of subcutaneous stimulation

a) In this test a proper model is used to measure the implied stimulation effect of a device, material and/or its diffusate on the implanted part of subcutaneous tissue. This stimulation test must be carried out by considering the practical means of the use or contact(skin. Etc) and duration period, and accommodating them to the test.

b) According to the above method, inject a certain quantity of CE product diffusate into the rabbit skin , observe the skin reaction and evaluate the tested material stimulation to the tissue.

3) Skin allergy test

a) In this test a proper model is used to determine the implied allergy by contact.

b) By means of a certain quantity of collecting needle dffusate in touch with guinea-pig skin, a determination can be made to know if the tested article can cause a contact-related skin allergic reaction.

4) Tests for local effects after implantation

All implant medical device shall comply with the local effects after implantation requirements.

3.2 Test methods:

3.2.1 The device manufactured by our company have sampled to TUV SUD for testing and all passed the test on EN ISO 10993-1:2009+ AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010.

3.3 Results:

According to the biocompatibility test reports, the device complies with the biocompatibility requirements.

Please see the Biocompatibility Test Reports.

4. Stability test

Purpose

Get the evidence that the expiration date for use of the device is 5 years.

The purpose of a stability study is to ascertain that the properties of the medical devices remain within specified limits for a sufficient long period of time under the influence of a variety of environmental conditions.

Methodology

General: Accelerated aging techniques are based on the assumption that the chemical reaction involved in the deterioration materials follows the Arrhenius reaction rate function. The function states that 10° C increase or decrease in

approximately two or ½ time change in the rate of a chemical reaction. As temperature increases, the aging factor also increases and the aging duration decreases. However benefits in efficiency from raising the aging temperature must be balanced by risks involved with extra plating increasingly high aging properties to room temperature.

Formulae:	**e.g.**
AAF= $Q_{10}^{[T_{AA} - T_{RT}]/10}$	Q10=2.0, ambient temperature=*25°C
Where:	Test temperature=55°C
AAF= the accelerated aging factor	AAF=2. $0^{(55 - 25)/10}$
TAA= Accelerated aging temperature (°C)	AAF=2. $0^{3.0}$, AAF=8. 0
TRT= ambient temperature (°C)	AAT=365 * 5 days/8.0
Accelerated aging t ime (AAT) = Desired (RT) / AAF	
* This temperature normally is between 20-25°C for normal hospital type storage. A temperature of 25°C is conservative and may be appropriate when detailed information about the storage environment not available (Reference: standard ASTM- F1980-99)	AAT=229 days

Accelerate aging factor and time determination

- WHO recommendations

1) 'WHO' has divided the world in four climatic zones for this purpose

Zones	**°C**	**% RH**
Zone I (Temperature)	20	42
Zone II (sub-tropical with possible high humidity)	22	52
Zone III (Hot / Dry)	27.9	35
Zone IV (Hot / Humid)	27.4	76

2) 'WHO' has also recommended that:

For some dosages forms like liquids and semi-solids, the design of study may also require consideration of low temperature e.g. below zero (-10 to -20), freeze- thaw cycles and temperatures between 2-8°C

3) WHO has also recommended that:

a) 15°C above the expected temperature of storage with appropriate humidity for six months

b) 40°C and 75% RH for six month or for three month

c) 45°C and 75% RH for three month or for three month

Note: In stability testing of medical devices mainly influence of temperature on the product.

Test to be conducted on the sample under shelf life study

The design of the stability study bases on the known properties from which they are manufactured, criticality of usage and their packing etc.

1) Test on pouch

NO	Test item	Requirement	References
1	Tensile seal strength test	Tensile seal strength test should be min. 1.1 lbs/in.	EN ISO 11607
2	Impermeability and continuity of seals formed by fusion test	No dry penetration completely through the seal	EN ISO 11607
3	Vacuum leak test	Should not leak at a vacuum pressure of -20Kpa	EN ISO 11607
4	Agar contact-attack test	No serratia marcescens growth is found on the side of packing material contacting with agar	EN ISO 11607

Results: the validity of 5 years is reasonable.

5. Risk Analysis

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

6. Conclusion

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

Packaging Qualification Summary

1. Summarization

Package material of Disposable vaginal speculum manufactured in our company is low-density polyethylene package bag. The package material and packaging process were validated according to requirements of EN 868-1,-5. Accelerating aging test was implemented to test the shelf life of product.

2. Qualification certification of package materials

2.1 Supplier should provide inspection report of conforming package box and corrugated paper case.

2.2 Bio-burden test of package bag

In the packaging validation, our company has conducted tests on *Microbial Barrier Properties (Agar Contact-Attack Test), and Seal Strength Test*, and the result is PASS.

Please check the Packaging Qualification Report (ShengboCE2-Appendix.3).

2.3 Conformity of package materials with sterilization process

Please check the Sterilization Validation Report (ShengboCE2-Appendix.4).

2.4 Biocompatibility of package materials

The device manufactured by our company have sampled to Sanitation&Environment Techlogy Institute,Soochow University for Medical Devices for type testing and all passed the test on EN ISO 10993-5:2009, ISO 10993-10:2010. The test unit includes the packaging materials.
Please check the Product Biocompatibility Reports (ShengboCE2-Appendix.2).

3. Qualification of packaging process

Our company conducts packaging qualification every year to ensure the packaging parameters in qualified range.

3.1 Determination of temperature, speed and pressure of sealer.

3.2 Qualification standards: EN ISO 11607-1:2009, EN ISO 11607-2:2006.

3.3 Packaging qualification report

Please see Packaging Qualification Report (ShengboCE2-Appendix.3).

3.4 Test report for seal airproof of package bag

In the packaging qualification, our company has conducted tests on *Vacuum Leak Test, Dye Penetration Test, Microbial Barrier Properties (Agar Contact-Attack Test), and Seal Strength Test*, and the result is PASS.

Please check the Packaging Qualification Report (ShengboCE2-Appendix.3).

Sterilization Verification Summary

1 Introduction of sterilization validation

The company performs the sterilization validation according to EN 550 / ISO 11135 to ensure the sterility of product meeting requirement of EN 550 / ISO 11135 together with Ethylene oxide gas sterilization validation team from Zhe Jiang Huan Yi Medical Product Sterilization Co.,Ltd. which certificated by TUV Rheinland LGA Products GmbH.

The test results show that the sterile products of our company achieved SAL 10^{-6}. The sterilization result of subcontracted sterilization supplier is conforming to EN ISO13485:2012, ENISO11135-1,SAL achieved 10^{-6}. The samples are retained for qualitative reference.

2. Sterilization validation

Please refer to the attachment of ShengboCE2--Appendix.4:Sterilization Validation Report and ShengboCE2--Appendix.3 Package Qualification Report.

Clinical Evaluation

Compiled by:_____ Date: 2015.11.20

Reviewed by:_____ Date: 2015.11.20

Approved by:_____ Date: 2015.11.20

1. Purpose

According to the requirements of the appendix X of MDD 93/42/EEC, we compile this clinical data to certify that the products of our company fulfilled the requirements of the appendix 1. I.e. the CE product, Disposable vaginal speculum, must give a evidence of the clinical performance and safety is qualified, appropriate and adequate to conform with the pertinent essential requirements of the Directive, and risks and side effects is acceptable when weighed against the intended benefits of the device.

2. Intended uses of products and side effect

- **Intended use:** see product instruction and description.

3. Product comparison with other company

The device manufactured by our company share the same principle, intended use, main structure and components of most of already marketed.

Compared with Changzhou Changjia Medical Appliance Co., Ltd. which holds a CE certificate by TUV SUD (No. G2 13 12 76830 005)

Item	Changzhou Changjia Medical Appliance Co., Ltd.	Changshu Taining Medical Equipment Co.,Ltd
Device Name	Disposable vaginal speculum	Sterile Vaginal Speculums
Intended use	For obstetrics and gynecology examination	Same
Target consumer	Patients with gynecological diseases	Same
Contraindication	Patients sensitive to plastics	Same
Product specification	Vaginal speculum is made up of up leaf, down leaf, adjusting staff. Large, medium, smal	Same
Materials	Made from non-toxic medical polypropylene complying with national standard GB 15593-1995(EQV ISO 3286-1983)	Same
Principle	To open the vaginal for examination	Same
Physical function	deflection resistance, no heat source.	Same
Use environment	Room environment requirement	Same
Applied standard	YY 0336-2013 Disposable Vaginal Speculums	
EO method	EOG	Same

4. Distribution area and quantity and feedback from customers

The products are not distributed to EU market yet.

Year	Sell to the countries and regions	Selling number (thousand)	Complaint number	Complaint content
2011	China, Russia	200	/	/
2012	China, EU	300	/	/
2013	China, Middle east, EU	440	/	/
2014	China, Middle east, EU	650	/	/
2015	China, Middle east, USA	400	/	/

5. Clinical Application Risks

During clinical use of these medical devices, clinical application risk may be produced, these risks shall be investigated during clinical evaluation. Following is potential clinical risk of these devices.

Device name	Potential clinical application risk
Disposable vaginal speculum	1. Materials sensitivity and irritation 2. Infection of patients because of failed SAL or operation environment control. 3. Infection during usage of the device. 4. Fail of product performance. 5. Patients who can not use the device use the device. 6. Wrong instruction for use. 7. Inadequate labeling information and caution information. 8. Used by unskilled person.

For the clinical risk control, please see Risk Analysis Report.

6 Clinical literature searches

6.1 Clinical literature searches plan

6.1.1 Device name:

Disposable vaginal speculum

6.1.2 Scope of the literature search:

Vaginal Speculums,

6.1.3 Methods

(i) Date of search: Feb.12,2014-Sep.12,2015

(ii) Name of person(s) undertaking the literature search:

Name	Title	Responsibility
	R&D manager	Literature search
	Quality manager	Evaluate the literature search results
	Clinical doctor	Approval of the literature search results

(iii) Period covered by search:
Feb.12,2014-Sep.12,2014

(iv) Literature sources used to identify data:
1) scientific databases –CNKI, MEDLINE, EMBASE, WANFANG DATA, VIP DATA.
2) specialised databases - MEDION
3) systematic review databases-Cochrane Collaboration
4) clinical trial registers - CENTRAL
5) adverse event report databases - MAUDE
6) customers feedback
7) other reference texts

(v) Database search details:
1) search terms (key words, indexing headings): vaginal speculum, suture staple, circumcision operation.
2) medium used: On-line.

(vi) Selection criteria used to choose articles:
1) the article shall be focused on products;
2) the products involved in the articles shall focus on the same type of our products, or comparison between our type and other types;
3) the article is better to focus on products clinical evaluation, functional evaluation, characteristics influenced on product function, risk assessment and control;
4) the article resource shall be effective, valid, and it is better from professional institutes researches;
5) try to adopt the newest articles resources.

6.2 Clinical literature outputs

Article 1: Does lubrication of the vaginal speculum reduce pain during a gynecologic oncology examination?

Source: Eur J Obstet Gynecol Reprod Biol. 2015 Jan;184:84-8. doi: 10.1016/j.ejogrb.2014.11.006. Epub 2014 Nov 20.

Author: Gungorduk K1, Ozdemir A2, G k M2 Sanc M2.

1Department of Gynecologic Oncology, Tepecik Education and Research Hospital, Izmir, Turkey. Electronic address: maidenkemal@yahoo.com.

2Department of Gynecologic Oncology, Tepecik Education and Research Hospital, Izmir, Turkey.

Abstract:

OBJECTIVE:

To evaluate the effectiveness of lubricant gel for reducing pain during a vaginal speculum examination (SE) in patients with gynecologic cancers.

STUDY DESIGN:

This non blind randomized controlled trial included 200 women who underwent SE for post-treatment surveillance. One-hundred patients each were allocated to the water and

lubricant gel groups. All patients were asked to score their pain during speculum insertion, dilatation, and extraction using a visual analog scale (VAS). Pain intensity during speculum insertion was the primary outcome measure.

RESULTS:
There were no statistically significant differences in demographic characteristics between the water (n = 97) and lubricant gel (n = 98) groups. The VAS pain scores obtained during all phases of the SE were significantly lower in the lubricant gel group compared with the water group during the insertion (3.95 ± 1.57 vs. 5.28 ± 1.71, P < 0.001), dilatation (5.96 ± 1.48 vs. 6.74 ± 1.69, P < 0.001) and extraction phases (2.60 ± 1.17 vs. 3.50 ± 1.25 P < 0.001). When a separate analysis was performed for the patients who underwent radiation therapy, the mean VAS pain scores were significantly lower in the lubricant gel group during the insertion (4.46 ± 1.45 vs. 6.22 ± 1.79, P < 0.001), dilatation (6.31 ± 1.66 vs. 7.52 ± 1.61, P = 0.002) and extraction phases (2.68 ± 1.31 vs. 3.66 ± 1.06, P = 0.001).

CONCLUSION:
The use of speculum lubricant gel significantly decreased pain during the SE in gynecologic oncology patients.

Search path: http://www.ncbi.nlm.nih.gov/pubmed/25481363

Article 2: Surgical technique of saphenous vein harvesting using a Cusco vaginal speculum

Source: Kyobu Geka. 2014 Nov;67(12):1066-9.
Author: Kikuchi K1, Suzuki K, Endo Y, Matsuyama T, Osaka S, Kurata A.
1Division of Cardiovascular Surgery, Yamato Seiwa Hospital, Yamato, Japan.
Abstract:
We used Cusco vaginal speculum in harvesting saphenous vein graft (SVG) as an assist device for making a skin tunnel. After making 2 incisions of 3 to 4 cm, the SVG was dissected in a usual procedure. Then Cusco vaginal speculum was inserted into the skin tunnel between the 2 incisions. The SVG was dissected in a usual fashion under direct vision with the speculum. This procedure requires only small incisions, short learning curve and low cost. The new technique using Cusco vaginal speculum can be a reliable option for harvesting SVG.
Search path: http://www.ncbi.nlm.nih.gov/pubmed/25391468

6.2.8 Summary of literature evaluation

No.	Literature Article	Brief description	Note
1	Does lubrication of the vaginal speculum reduce pain during a gynecologic oncology examination?	The use of speculum lubricant gel significantly decreased pain during the SE in gynecologic oncology patients.	Article 1

2	Surgical technique of saphenous vein harvesting using a Cusco vaginal speculum	Using vaginal speculum can be a reliable option for harvesting SVG.	Article 1

6.2.9 Resume of evaluator and approval:

Name	ZHOU Lixia	Age	40
Gender	Male	Position	Technical director
Company	Jiangsu Changmei Medtech Co., Ltd.		

Work experience:

More than 20 years design work experience, among which 10 years focused on medical devices design, proficient in injection molding, extrusion and molding of catheters.
In the recent 10 years, he designed the Rectal Tubes, Umbilical Cord Clamp, Urine Bags, Vaginal Speculums, Urine Meter, Feeding Bag, Enema Bag, and the process manufacture equipment of these products.

Name	LU Jianyun	Age	50
Gender	Male	Position	Deputy chief physician
Hospital	Changzhou No.2 People's Hospital		

Work experience:

More than 20 years medical experience with rich clinical experience in treatment of fatty liver, chronic liver disease, peptic disease. He published more then 10 medical papers in the provincial and municipal journals.

Now, work focuses on endoscope related treatments, such as gastrointestinal polyps resection in endoscopic electrotomym, esophageal metal stent inserting, esophageal stricture dialation, digestie tract tumor (benign) endoscopic treatment, endoscopic retrograde cholangiopancreatography, endoscopictreatment of hemorrhage of digestive tract bleeding.

1998, graduated from Nanjing Medical University.
1997, study in Renji Hospital affiliated to Shanghai Jiaotong University.
2000, endoscope study in Changhai Hosptial affiliated to the 2nd Military Medical University.

7. Conclusion

It can be concluded from above narration that the products with CE marking of this company, products, can be safe, little risks and in accordance with requirements by used as medical device.

8. Post market clinical follow-up (PMCF)

Reference on MEDDEV 2.12-2, the company has built the post market clinical follow-up plan in order to recognize these infrequent complications or problems only apparent after widespread use, or these long-term performance issues.

8.1 Post market clinical follow-up plan

8.1.1 Device name: Disposable vaginal speculum

8.1.2 Staff arrangement and periodity of PMCF

(i) Name of person(s) undertaking the PMCF:

Name	Title	Responsibility
All sales person		Collect all customers feedbacks and adverse events data
	Technical Manager	Evaluate all possible recognized risks in production in all periods
	Director doctor, Master's advisor	Documentation, relevant products problems collection. Follow up of patients samples who are enrolled in the clinical trails.
	General manager	Approval of the PMCF plan and any found results or problems.

(ii) Period covered by PMCF:

Oct.28, 2014-Oct.27,2017

In order to recognize adequately these infrequent complications or problems only apparent after widespread use, and consider the 3 years validity of the product, we decide to apply PMCF in four years, and had began on Oct.28, 2014, and will be finished on Oct.27,2017.

8.1.3 What will be focused on PMCF

⑴ PMCF should always be considered for devices where identification of possible emerging risks and the evaluation of long term safety and performance are critical. In identifying such emerging risk, the following criteria should be taken into account :

- **innovation**, when the design of the device, the material, the principles of operation, the technology, or the medical indication is new
- **severity** of the disease,
- **sensitive target population**
- **risky anatomical location**
- **well known risk** from the literature
- **well known risk** of similar marketed devices
- **Identification** of an acceptable risk during pre-CE clinical evaluation, which should be monitored in a longer term and/or through a larger population.
- **Obvious discrepancy** between the pre-market follow up timescales and the

expected life of the product

ⓘ following actions will be taken:

• All received complaints and adverse events data will be systematically reviewed, and all product related adverse events will be notified to the relevant Competent Authority (ies). This includes all sources of information known by the manufacturer, including published literature.

• Monitoring of postmarket performance will take into account relevant data publicly available with similar devices especially when the CE marking was based on equivalence.

• PMCF in the form of follow up of all or a justifiable subset of patients already enrolled in pre-marketing Clinical Investigations; or on specific sub-groups and/or prospective study or registry of a sample of products.

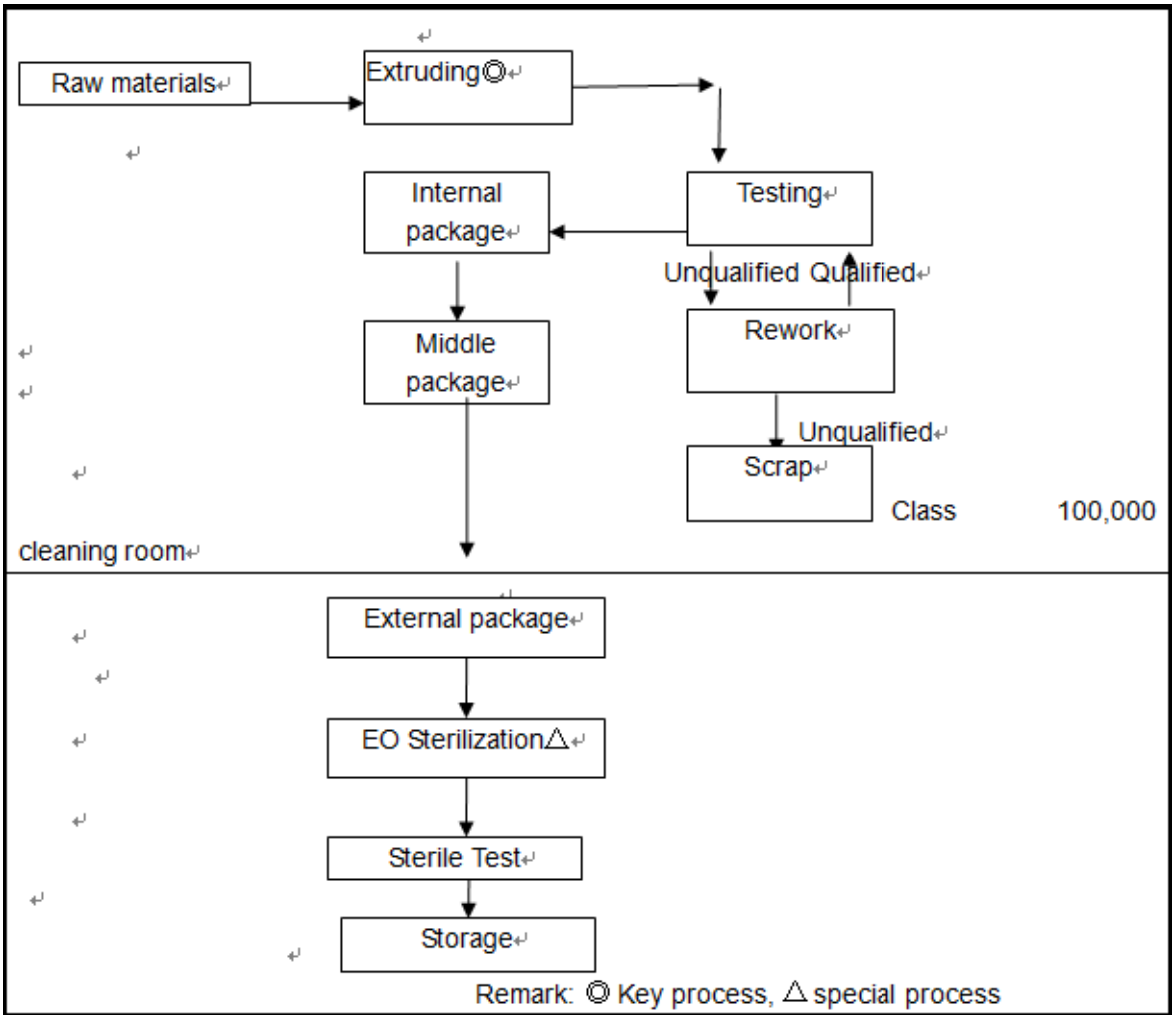
8.2 PMCF outputs

By far, our company does not sell Disposable vaginal speculum into the market, but according to customers feedback and PMCF of which manufacture equivalent device to our company, no other risks.

Production and quality control

1 Production flow

Disposable vaginal speculum production flow chart:



2 Quality control

The company has conducted EN ISO13485:2012/AC:2012 QMS since Apr.2015, and all production processes are on control under this QMS and MDD 93/42/EEC.

2.1 Process control

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

2.2 Environmental control

The device is manufactured in the cleanroom with class100,000 Control of production environment is given in *Working Environment Control Procedure*

2.3 Control of production equipment

Control of production equipment is given in *Production Equipment Control Procedure*

2.5 Control of production process

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

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

c) Control of special processes: control of processes, including packaging and sterilization, is given in *Process Validation Control Procedure, and Sterilization Process Validation Control Procedure*

2.6 Control of unaccepted products

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

2.7 Control of product identification and traceability

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

2.8 Identification of raw materials

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

2.9 Identification of finished products

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

2.10 Commodity identification

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

2.11 All identifications are the only record, and should be kept for up to five years.

2.12 Trace

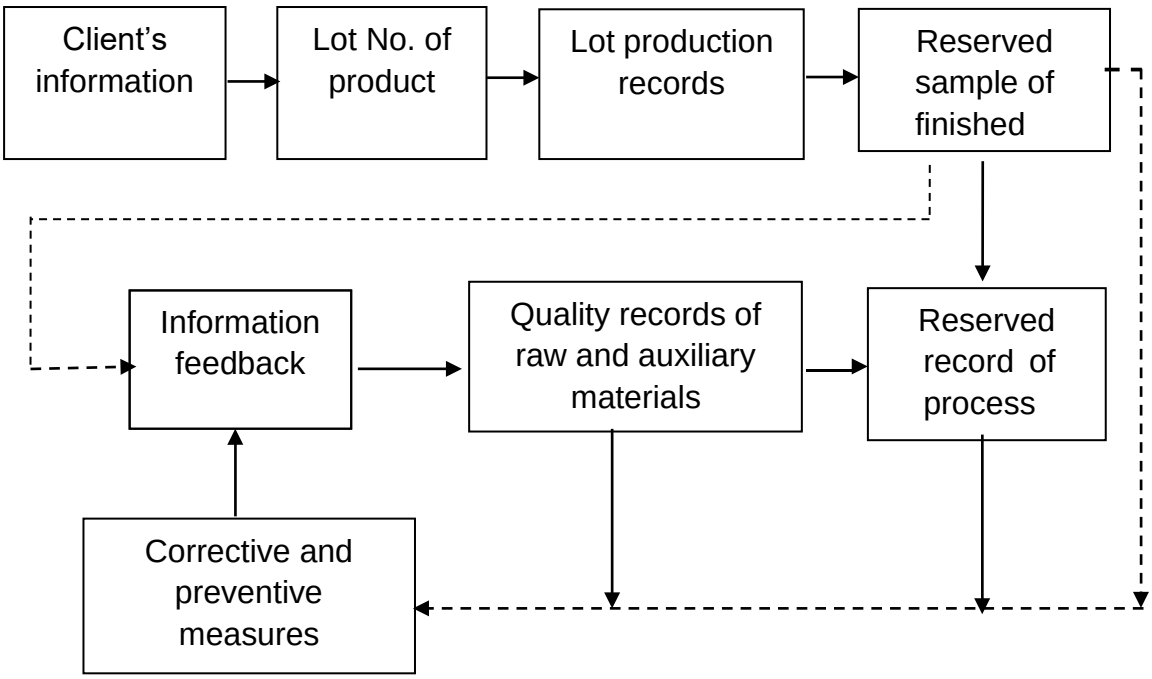
a. Back trace

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

b. Forward trace

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

Traceability procedure:



2.13 Control over the final release of products

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

2.14 Preventive control during flow

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