93/42/EEC including 2007/47/EC Annex I Essential Requirements Checklist 93/42/EEC 包括 2007/47/EC 附录一　基本要求检查表	VINNO Technology (Suzhou) Co., Ltd.

Product name: **产品名：**	**Ultrasound diagnostic system** **数字化彩色超声诊断仪**
Type(s)/Model(s): **类型/型号**	**VINNO E20, VINNO E10, VINNO E10E, VINNO X1, VINNO X2, VINNO X3** **VINNO E20, VINNO E10, VINNO E10E, VINNO X1, VINNO X2, VINNO X3**
Product group: **产品族**	**VINNO E20 series** **VINNO E20 系列**
Issue date of Technical File: **技术文档发布日：**	**2017-05-26**
Revision of Technical File: **技术文档修订版本：**	**1**
Legal Manufacturer: **法定制造商**	VINNO Technology (Suzhou) Co., Ltd. *Name 名字* 5F Building A, 4F Building C, No.27 Xinfa Rd *Street 街道* 215123 (*Postal code 邮编*) Suzhou Industrial Park, Jiangsu (*Place 地点*) China *Country 国家*
Accessories: **附件：**	Ultrasound Probes, ECG leads, Foot switch, 超声探头，ECG 导联线，脚踏开关

2017-05-26	**Wang Wei/王玮**	**Wang Wei/王玮**
Date 日期	*Name Reviewer 1/审核人 1 的名字*	*Signature Reviewer 1/审核人 1 签字*
Date 日期	*Name Reviewer 2/审核人 2 的名字*	*Signature Reviewer 2/审核人 2 签字*

Digitally signed by Lungu Ion
Date: 2023.01.08 14:18:18 EET
Reason: MoldSign Signature
Location: Moldova

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)	Requirements fulfilled Ok / Fail 符合 / 不符合
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. 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 the following 应包括如下：	A	ISO 14971: 2012 ISO 13485: 2012 ISO/TR 14969 ISO 14155 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007	ISO 13485 Certificate DHF, DMR Technical file Safety and EMC Test Report： 15091712 001 15084504 001 15084322 001 15084504 002	OK
	• 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 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险	A	ISO 14971:2012 IEC 62366:2007+A1:2014	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043	OK
	• 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). 考虑技术知识、经验、教育和培训，预期用户（为非专	A	IEC 62366:2007+A1:2014	UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043	OK

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	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: 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：	A	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969 ISO 10993-1:2009/AC:2010 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007 2006/42/EC	ISO 13485 Certificate RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Biocompatibility test report Safety and EMC Test Report： 15091712 001 15084504 001 15084322 001 15084504 002	OK
	• identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;	A	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate	OK
	• eliminate or reduce risks as far as possible (inherently safe design and construction), 尽可能地降低或避免风险（固有的安全设计和结构）	A	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate	OK
	• where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, 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。	A	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate	OK

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	• Inform users of the residual risks due to any shortcomings of the protection measures adopted. 告知用户由于所提供防护措施的缺陷而带来的残留风险。	A	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate	OK
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	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate Safety and EMC Test Report: 15091712 001 15084504 001 15084322 001 15084504 002	OK
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	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007 2006/42/EC	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate Safety and EMC Test Report: 15091712 001 15084504 001 15084322 001 15084504 002	
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.	A	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969 IEC 60601-1: 2005/A1: 2012	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate Safety and EMC Test Report: User manual	OK

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	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。		IEC 60601-1-2:2007 IEC 60601-2-37: 2007		
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	ISO 14971:2012 ISO 13485:2012 ISO/TR 14969 ISO 10993-1:2009/AC:2010 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007 IEC 62366:2007+A1:2014	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate Biocompatibility test report Safety and EMC Test Report UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043	OK
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	ANNEX X	QP8.5-06 LEC-TSUGA-001	OK
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 following 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，另外应特别注意如下				

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	• the choice of materials used, particularly as regards toxicity and, where appropriate flammability, 合理选择原料，特别是易燃物质和有毒物质的选择;	A	ISO/TR 14969 ISO 10993-5:2009 Directive 2011/65/EU	ISO 13485 Certificate Biocompatibility test report RoHS assessment	OK
	• the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. 从器械预定功能出发考虑所选材料同人体生物组织、细胞和体液的相容性。	A	ISO 10993-1:2009/AC:2010 ISO 10993-5:2009 ISO 10993-10:2010	Biocompatibility test report	OK
	• Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand. 如适用，事先已确认有效的生物物理学或模型研究的结果	NA	ISO 14630	NA	NA
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。		ISO/TR 14969 ISO 10993-1:2009/AC:2010 ISO 10993-5:2009 ISO 10993-10:2010	ISO 13485 Certificate Biocompatibility test report	OK
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		ISO 14971:2012 ISO 10993-1:2009/AC:2010 ISO 10993-5:2009 ISO 10993-10:2010 IEC 60601-1: 2005/A1: 2012	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA ISO 13485 Certificate Biocompatibility test report Safety and EMC Test Report	OK

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	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。		IEC 60601-1-2:2007 IEC 60601-2-37: 2007		
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 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	NA	NA	The Essential Requirement Checklist stated that the device are not loading or contain other drugs.	NA

[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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	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（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	NA	NA	The Essential Requirement Checklist stated that the device are not loading or contain other drugs.	NA

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	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 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				

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	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 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	NA	NA	The Essential Requirement Checklist stated that the device are not loading or contain other drugs.	NA

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

[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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	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 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。		ISO 14971:2012 ISO 10993-1:2009/AC:2010 ISO 10993-5:2009 ISO 10993-10:2010	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Biocompatibility test report	OK
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		ISO 10993-1:2009/AC:2010 ISO 10993-5:2009	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA	OK

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	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。		ISO 10993-10:2010 ISO 14971:2012	Biocompatibility test report	
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. 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。	NA	NA	The Essential Requirement Checklist stated that there are no medical substances or tissues of animal origin incorporated into the device.	NA
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,	NA	NA	The Essential Requirement Checklist stated that the device is Non sterilization device.	NA

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	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。				
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。	NA	NA	These devices are Non sterilization device.	NA
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。	NA	NA	These devices are Non sterilization device.	NA
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。	A	ISO 14971:2012 IEC 60601-1: 2005/A1: 2012	User manual Safety test report	OK
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。	NA	NA	These devices are Non sterilization device.	NA

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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. 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。	A	IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007 ISO 14971:2012	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Safety and EMC test report User manual	OK
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	A	IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007 ISO 14971:2012 IEC 62366:2007+A1:2014 2006/42/EC	Safety and EMC test report RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043	OK

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	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. 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。	A	ISO 14971:2012 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007	Safety and EMC test report RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA	OK
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。	A	IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007	User manual Safety and EMC test report	OK

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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。	A	IEC 60601-1-6:2010 + A1:2013 IEC 62366:2007+A1:2014	UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043	OK
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。	A	80/181/EEC	User manual	OK
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。	A	IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007	Safety and EMC test report	OK
11.2	*Intended radiation* 预期的辐射	NA	NA	The Essential Requirement Checklist stated that there are no X Ray generater incorporated into the device.	NA

[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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11.2.1	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，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。	NA	NA	The Essential Requirement Checklist stated that there are no X Ray generater incorporated into the device.	NA
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。	NA	NA	The Essential Requirement Checklist stated that there are no X Ray generater incorporated into the device.	NA
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。	NA	NA	The Essential Requirement Checklist stated that there are no X Ray generater incorporated into the device.	NA
11.4 11.4.1	*Instructions* *使用说明* The operating instructions for devices emitting radiation	NA	NA	The Essential Requirement Checklist stated that there are no X Ray generater incorporated into the device.	NA

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	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。				
11.5 11.5.1	*Ionising radiation* *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。	NA	NA	The Essential Requirement Checklist stated that there are no Ionising radiation from the device.	NA
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。	NA	NA	The Essential Requirement Checklist stated that there are no Ionising radiation from the device.	NA
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	NA	NA	The Essential Requirement Checklist stated that there are no Ionising radiation from the device.	NA

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	监控照射剂量、离子束类型、能量大小以及离子束的质量。				
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 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。	A	IEC 60601-1: 2005/A1: 2012 IEC 62304:2006	Safety test report: 15091712 001 15084322 001 Compliance checklist of software life cycle processes: VER-TSUGA-043	OK
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。	A	IEC 60601-1: 2005/A1: 2012 IEC 62304:2006	Safety test report: 15091712 001 15084322 001 Compliance checklist of software life cycle processes: VER-TSUGA-043	OK
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。	NA	NA	The Essential Requirement Checklist stated that there are no internal power supply incorporated into the device.	NA
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，	NA	NA	The Essential Requirement Checklist stated that our devices are not those where the safety of the patients depends on an external power supply	OK

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	报告电源中断。				
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。	NA	NA	The Essential Requirement Checklist stated that our devices are not intended to monitor clinical parameters of patient	NA
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。	A	IEC 60601-1-2:2007	EMC test report: 15084504 001 15084504 002	OK
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。	A	ISO 14971:2012 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Safety and EMC test report	OK
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.	A	ISO14971:2012 IEC 60601-1: 2005/A1: 2012 Machinery Directive 2006/42/EC	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Safety test report	OK

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)	Requirements fulfilled Ok / Fail 符合 / 不符合
	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。				
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造成的危害，除非所发出的振动是特定功能的需要。	A	ISO14971:2012 IEC 60601-1: 2005/A1: 2012	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Safety test report	OK
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。	A	ISO14971:2012 IEC 60601-1: 2005/A1: 2012	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Safety test report	OK
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。	A	ISO14971:2012 IEC 60601-1: 2005/A1: 2012 IEC 62366:2007+A1:2014	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043 Safety test report	OK
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.	A	ISO14971:2012 IEC 60601-1: 2005/A1: 2012	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA Safety test report	OK

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)	Requirements fulfilled Ok / Fail 符合 / 不符合
	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。				
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. 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。	NA	NA	The Essential Requirement Checklist stated that there are no energy supplies or substances from the device.	NA
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。	NA	NA	The Essential Requirement Checklist stated that there are no energy supplies or substances from the device.	NA
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.	A	IEC 60601-1: 2005/A1: 2012 IEC 62366:2007+A1:2014	UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043 Safety test report	OK

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)	Requirements fulfilled Ok / Fail 符合 / 不符合
	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。				
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，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。	A	ISO/TR 24971:2013 IEC 60601-1: 2005/A1: 2012 IEC 60601-1-2:2007 IEC 60601-2-37: 2007	RMF including QP 7.1-01, RMP-TSUGA, RMR-TSUGA, RAC-TSUGA, SFA-TSUGA User manual and label Safety and EMC test report	OK

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)	Requirements fulfilled Ok / Fail 符合 / 不符合
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	ISO 7000 ISO 7010 ISO 15223-1 IEC 60417 IEC 60878	User manual Label	OK
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。 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； c) where appropriate, the word "STERILE"; (c)必要时，注明“已灭菌”字样； d) where appropriate, the batch code, preceded by the word "LOT", or the serial number;	A for all except items c, e, f, g,h,I,j ,k,m and n	ISO 15223-1 IEC 60601-1: 2005/A1: 2012	Label	OK

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)	Requirements fulfilled Ok / Fail 符合 / 不符合
	(d)必要时，注明批号或系列号，批号以“LOT”打头； 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。 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。 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。 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 i) any special storage and/or handling conditions; i) 特殊储存条件和/或管理要求； j) any special operating instructions; j) 特殊操作说明； k) any warnings and/or precautions to take; 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;				

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	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				
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。	A	ISO 15223-1 IEC 60601-1: 2005/A1: 2012	User manual	OK
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。	A	IEC 60601-1: 2005/A1: 2012 IEC 62366:2007+A1:2014	UEF including SDDS-TSUGA-001, VAP-TSUGA-005, VER-TSUGA-043 Safety test report	OK
13.6	Where appropriate, the instructions for use must contain the following particulars: 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； b) the performances referred to in section 3 and any undesirable side effects;	A for all except items e, g, h, j, m and o.	EN 1041 2006/42/EC	User manual Service manual	OK

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	b) 本附录第 3 款所指使用性能及其可能带来的副作用。				
	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。				
	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。				
	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。				
	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。				
	g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation				

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	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。 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 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；				

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	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 the performance of the device; k)器械性能发生变化时的注意事项； 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 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) 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。 o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in				

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	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； 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。 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				