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Risk Management File

Surgical blades & Scalpels with Plastic Handle

Model:18#,19#,20#,21#,22#,23#,24#,25#,26#,27#,
34#,36#27#22A#9#,10#,11#,12#,13#,14#,15#,16#
6#10A#12B#12D#15A#

Prepared by:

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Revision Record

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A.5	Updated pms report	2021-2-20	Xia Ping	Zhu Xiaohuai

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风险管理计划

Risk management plan

编制 Prepared by：

审核 Checked by：

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1、范围：Scope

产品描述 Product Description:

无菌手术刀片及塑柄手术刀是采用碳钢或不锈钢制成的，适用于普通外科医生和专业切割外科医生。手术刀片的规格、硬度、锋利度、弹性、韧性及相关尺寸符合 YY0174 / YY0454 标准。
Sterile surgical blades & scalpels with plastic handle is made of stainless steel or carbon steel material which work in knife handle applied to the ordinary and professional incision surgeons .Sterile surgical blade specification ,hardness ,blade size and related handle size must meet the YY0174/YY0454 standards .Completed specification ,sharpness ,well elasticity and tenacity in our blade.

本风险管理计划主要是对无菌手术刀片及塑柄手术刀产品在其整个生命周期内（包括设计开发、产品实现、最终停用和处置阶段）进行风险管理活动的策划。

The risk management plan is mainly used for planning risk management activities of Sterile surgical blades & scalpels with plastic handle product in the whole life cycle (including the stages of design, development, product realization, final shutdown and disposal).

2、职责与权限的分配 Distribution of Responsibilities and Permissions

2.1 总经理为风险管理提供适当的资源，对风险管理工作负领导责任。保证给风险管理人员是经过培训合格的，保证风险管理工作执行者具有相适应的知识和经验。

General Manager provides proper resources for risk management and is responsible for leading risk management. Risk management personnel shall be qualified by training and risk management executor has adaptive knowledge and experience.

2.2 技术部负责产品设计和开发过程中的风险管理活动，形成风险分析、风险评价、风险控制、综合剩余风险分析评价的有关记录，并编制风险管理报告。

Technology Department is responsible for risk management activities in the product design and development process to form relevant records of risk analysis, risk evaluation, risk control, comprehensive residual risk analysis and assessment, and prepare risk management report.

2.3 质管部、临床经理、销售部、生产部等相关部门负责从产品实现的角度分析所有已知的和可预见的危害，以及生产和生产后信息的收集并及时反馈给技术部进行风险评价，必要时进行新一轮风险管理活动。

Quality Department, Clinical Manager, Sales Department, Production Department and other departments are responsible for analyzing all known and foreseeable harms from the perspective of product realization, collecting production and post-production information and feeding back the information to the Technology Development in time for risk evaluation, and carrying out a new round of risk management activities if necessary.

2.4 管理者代表和评审组成员定期对风险管理活动的结果进行评审，并对其正确性和有效性负责。

Management representative and members in the evaluation group shall review the results of risk management activities periodically and take charge of correctness and validity thereof.

2.5 企业管理部负责对所有风险管理文档的整理工作。

Enterprise management department shall be responsible for tidying all risk management files.

3、风险分析 **Risk Analysis**

3.1 参加风险分析的部门包括生产部、质管部、技术部、企业管理部、临床经理、销售部等，技术部主要分析设计开发阶段已知和可预见的危害事件序列，生产部主要分析产品生产阶段的已知和可预见的危害事件序列，和销售部主要分析产品生产后已知和可预见的危害事件序列，技术部负责收集各部门分析的结果并按照 ENISO14971-2012 附录 E.1 的资料对所有已知和可预见的危害事件序列进行分析，管理者代表组织各部门进行风险评价和风险控制措施的分析与实施并编制成相应的文件。

Departments involved in risk analysis include Production Department, Quality Department, Technology Department, Enterprise management department, Clinical Management Department, Sales Department, Technology Department and the like. Technology Development is mainly responsible for analyzing the known and foreseeable sequence of hazard events in the design development stage. Production Development is mainly responsible for analyzing the known and foreseeable sequence of hazard events in the product pronunciation stage. Sales Department is mainly responsible for analyzing the known and foreseeable sequence of hazard events after production of product. Quality Department is responsible for collecting results analyzed by various departments and analyzing the known and foreseeable sequence of hazard events according to the data in Annex E.1 of ENISO14971-2012. Management representative shall organize various departments to carry out risk evaluation and analysis of risk control measurements and prepare corresponding document.

3.2 风险分析内容包括：

Contents of risk analysis include:

A）可能的危害及危害事件序列

Sequence of possible harms and hazard events

B）危害发生及其引起损害的概率

Probability of hazard occurrence and caused harm

C）损害的严重度

Severity of harm

3.3 在产品设计开发初始阶段由于对产品设计细节了解较少，采用 PHA（初步危害分析）技术对产品进行危害、危害处境及可能导致的损害进行分析。

As details of product design are known less in the initial stage of product design development, preliminary hazard analysis (PHA) technology is adopted for the analysis of hazard, hazardous situation and possible harm.

3.4 在设计开发成熟阶段采用失效模式和效应分析（FMEA）及失效模式、效应和危害分析（FMECA）对产品进行危害、危害处境及可能导致的损害进行分析。

In the design development mature stage, failure mode and effects analysis (FMEA) and failure mode effects and criticality analysis (FMECA) shall be adopted for the analysis of hazard, hazardous situation and possible harm.

3.5 在试生产或生产阶段采用危害分析和关键控制点（HACCP）进行风险管理的优化。

In the pilot production or production stage, hazard analysis and critical control point (HACCP) shall be adopted for optimizing risk management.

3.6 质管部、生产部负责配合技术部对产品所有已知和可预见的危害进行分析，保存好相关记录。

Quality Department and Production Department shall be responsible for analyzing all known and foreseeable hazards of the products and keeping relevant records well.

4、风险评价 Risk Evaluation

4.1 生产部、质管部、、销售部负责配合技术部对经风险分析判断出的危害进行发生概率与损害严重度的分析，最后根据本计划确定的风险可接受准则判断风险的可接受性，预期 2 个月，保存好评价记录。

Production Department, Quality Department and Sales Department shall be responsible for cooperating with Technology Department to analyze occurrence probability of hazards judged through risk analysis and harm severity, and judging acceptability of risk according to the acceptability criteria of risk according to the plan, with 2 months expected, and keeping the assessment records well.

4.2 根据《风险管理控制程序》中所定义的指导原则，评估风险/可接受风险的标准，定义风险管理的准则。

Criteria of risk management shall be defined according to the guiding principle, assessment risk/acceptable risk defined in the *Risk Management and Control Procedures*.

4.2.1 严重度定性 4 级 Determination of Severity Grade 4

等级 **Ratings**	代号 **Code**	系统风险定义 **System risk definition**
危重	4	导致永久性损伤或生命的伤害 Cause permanent damage and damage to life 示例说明： **Description:** 比如手术过程中刀片断裂，导致断刀片留在组织内，需要一些医疗手段的及时处理，严重可能导致某些组织永久性损伤或严重导致生命伤害 For example, the surgical blades breaks in the course of surgery and leaves the broken Surgical blades in the tissue, which requires the medical treatment timely, otherwise it may cause permanent damage to certain tissues or serious damage to life
严重	3	导致专业医疗介入的伤害或损伤 Cause injury or damage requiring professional medical intervention 示例说明： **Description:** 重复使用，可能导致感染、发热等，需介入医疗手段（使用抗感染药物等） Reuse of it may cause infection, fever and so on, requiring medical treatment intervention (use anti-infective drugs etc.)
轻度	2	导致不要求专业医疗介入的暂时伤害或损伤 Cause temporary injury or damage that does not require professional medical intervention 示例说明： **Description:** 使用后剩余的手术刀片应规范处置，刀尖导致接触人员产生轻微损伤，暂时伤害或损伤，一般无需医疗介入。 The remaining surgical blades after use shall be disposed properly, and the surgical blades tip may cause slight damage, temporary injury or damage, to the personnel who contact it, generally it requires no medical intervention.
可忽略	1	不便或暂时不适； Inconvenient or temporary discomfort; 示例说明： **Example Description:** 使用后的剩余手术刀片，应规范处置，可能导致环境污染。 The remaining surgical blades after use shall be disposed properly or it may cause environmental pollution.

4.2.2 损害发生概率的估计 Damage probability criteria

等级 Ratings	代号 Code	频次（每年）Frequency (per year)
经常 Usual	5	$\geq 10^{-3}$
有时 Sometimes	4	$<10^{-3}$ 和$\geq 10^{-4}$
偶然 Incidental	3	$<10^{-4}$ 和$\geq 10^{-5}$
很少 Very little	2	$<10^{-5}$ 和$\geq 10^{-6}$
非常少 Rare	1	$<10^{-6}$

注：每片手术刀片发生事件的次数或预期每年发生的次数{危害事件数/单位产品（年销售）}。

Note: Number of event occurrences of each Sterile surgical blades & scalpels with plastic handle or the expected number of occurrences each year (number of hazardous events/unit product (annual sales)).

示例说明：

Description:

2014 年、2015 年、2016 年 无菌手术刀片及塑柄手术刀年产量分别：41 万片、39 万、43 万，平均年产量 41 万。

The annual output of Sterile surgical blades & scalpels with plastic handle in 2014, 2015 and 2016 is 410,000 pieces, 390,000 and 430,000 respectively, with the average annual output of 410,000.

2014 年、2015 年、2016 年一共收集危害事件数*（如：刀片锋利度不合格）*：15 件 、 8 件、7 件。

The number of hazardous events (eg. unqualified surgical blades sharpness) collected in 2014, 2015 and 2016 is 15, 8 and 7.

平均危害事件数为 10 件。

The average number of hazardous events is 10.

危害概率=危害事件数÷单位年产品=10 件÷41 万=1/41000 即在$<10^{-4}$ 和$\geq 10^{-5}$ 之间，发生概率代号 3，概率等级为偶然。

Hazard probability =number of hazardous events ÷unit annual output=10 pieces÷410,000 = 1/41000 namely between<10-4and≥10-5, the probability of occurrence code is 3, so the probability level is accidental.

4.2.3 风险评价准则 Risk evaluation standards

损害发生概率 Occurrence probability of damage		严重程度 Rank			
		4	3	2	1
		危重 Critical	严重 Severe	轻度 Mild	可忽略 Negligible
经常 Usual	5	R_3	R_2	R_2	R_1
有时 Sometimes	4	R_3	R_2	R_2	R_1
偶然 Incidental	3	R_2	R_2	R_2	R_1
很少 Very little	2	R_2	R_2	R_1	R_1
非常少 Rare	1	R_1	R_1	R_1	R_1

注：风险水平(R)=损害严重度×概率

Note: Risk level (R)= damage severity × probability R1(1-5)：可忽略的风险

R1(1-5): Negligible risk

R2(6-15): 可接受的风险（进一步减低风险的研究，如具有技术可行性，应实施风险控制措施）

R2(6-15): Acceptable risk (study for further reduction of risk, risk control measures should be implemented if it is of technical feasibility)

R3(16-20)：不可接受的风险 R3(16-20): Unacceptable risk

4.3 在经过风险分析和风险评价过程判断出的产品所有的风险均应采取合理可行的措施降至可接受区，当风险被判断为不可接受时，应收集相关资料和文献对风险进行风险/受益分析，如果受益大于风险，则该风险还是可接受的，如果风险大于受益则设计应放弃。

All the risks of products, which are judged through risk analysis and risk evaluation process, shall be reduced to acceptable area by taking reasonable and feasible measures. When the risks are judged as non-acceptable, relevant data and documents shall be collected for risk/benefit analysis of risk. If the benefits outweigh the risks, the risks are still acceptable, if the risk is greater than the benefit, design shall be given up.

4.4 对损害概率不能加以估计的危害处境，应编写一个危害的可能后果清单以用于风险评价和风险控制，各部门应配合技术部采取合理纠正预防措施尽可能的降低风险，对于无法降低的风险进行风险，风险/受益分析，如果受益大于风险，则该危害可接受，如果风险大于受益，则风险不可接受。

For the hazardous situation that harm probability cannot be estimated, list of harmful consequences shall be prepared for risk evaluation and risk control, and reasonable departments shall cooperate with Technology Department to take corrective and preventive measures to reduce risk as much as possible.

Risk/benefit analysis shall be carried out for the risks which cannot be reduced. If the benefit is greater than the risk, then the hazard is acceptable, if the risk is greater than the benefit, the risk is non-acceptable.

4.5 在可接受区，风险是很低的，但是还应主动采取降低风险的控制措施。

The risk is very low in acceptable area, but it also needs to actively take measures to control and reduce the risk.

4.6 受益必须大于风险才能判断为可接受。

The risk shall be judged as acceptance when the benefit is greater than the risk.

5、风险控制 Risk Control

5.1 对于经判断为可接受的风险还应当采取可行的措施将风险降到最低。

Feasible measures shall be taken for minimizing the risk judged as acceptable.

对于经判断为不可接受的风险，各部门应配合技术部在设计开发阶段从以下几个方面进行风险控制方案分析，识别一个或多个风险控制措施，以把风险降低到可接受水平。

For the risk judged as non-acceptable, various departments shall cooperate with Technology Department to analyze risk control scheme in the design development stage from the following several aspects, identify one or more of the risk control measures, so as to reduce the risk to an acceptable level.

1）用设计方法取得固有安全性

Getting inherent safety feature with design method

--消除特定的危害；

Eliminating specific hazards;

--降低损害的发生概率；

Reducing the occurrence probability of harm;

--降低损害的严重度。

Reducing severity of harm

2）在产品本身或在制造过程中的防护措施。

Protective measures in the product itself or in the manufacturing process

3）安全信息

Security information

--在产品随附文件中给出警告、使用说明；

Giving warnings and instructions of the product in the accompanying document;

--限制医疗器械的使用或限制使用环境；

Limiting the use or service environment of medical device;

--对操作者进行培训。

Training the operator

5.3 在产品试生产或生产阶段，对产品制造过程进行控制，如运用 HACCP 技术。（危害分析和关键控制点）

Product manufacturing process shall be controlled by using HACCP technology in the pilot production or production stage of the product. (Hazard analysis and critical control point)

5.4 如果经方案分析确定所需的风险降低是不可行的，则各部门应收集相关资料对剩余风险进行风险/受益分析，若经评审所收集的资料和文献不支持受益大于风险，则设计应放弃。

If it is infeasible to reduce the risk through confirmation by means of program analysis, various departments shall collect relevant data to carry out risk/benefit analysis on the residual risk. If benefit greater than the risk is not supported by collected data and documents through review, design shall be given up.

5.5 各部门应确保经判定的危害处境产生的一个或多个风险得到充分考虑，保证风险控制的完整性。

Various departments shall ensure that one or more judged risks generated in the hazardous situation is fully considered, so as to guarantee the integrity of the risk control.

5.6 在风险控制方案实施中或实施后，应对实施效果进行验证，以确定控制措施的适应性和有效性，对任何剩余风险都应采取本计划中第 4 条的风险可接受准则进行评价，对判断为不可接受的应采取进一步的风险控制措施，如果控制措施不可行，则应收集和评审相关的资料和文献对剩余风险进行风险/受益分析，若受益大于风险，则剩余风险依然是可接收到，如果风险大于受益，则为不可接受。对于判断为可接受的剩余风险，销售部应配合技术部决定那些剩余风险应予以公开，依据 ENISO14971-2012 附件 J 的指南公开哪些剩余风险。同时对控制措施的实施是否会引起的一个或多个新的风险或对采取措施之前评价的风险是否有影响进行分析，必要时进行再次风险分析、风险评价和风险控制，所采取活动的结果应进行记录并保持。

During or after implementation of risk control plan, implementation effect shall be verified to determine the adaptability and validity of control measures, any residual risk shall be evaluated by using Article 4 Acceptable risk criteria in the plan, and non-acceptable risk shall be further adjusted by taking risk control measures. If control measures is impossible, you shall collect and review the relevant data and documents to carry out risk/benefit analysis on the residual risk. If the benefits outweigh the risks, the residual risk still can be received. but if the risk is greater than the benefit, it is non-acceptable. For the residual risks judged as acceptable, Sales Department shall cooperate with Technology Department to determine that those residual risks shall be open, and the residual risks required shall be open on the basis of the guideline of Annex J in ENISO14971-2012. Meanwhile, analysis shall be carried out to evaluate whether one or more new risks will be caused by implementation of control measures or whether there is

influence on risk evaluated before implementation of measures. Risk analysis, risk evaluation and risk control shall be carried out again if necessary. Results of the activities shall be recorded and maintained.

6、风险管理活动的验证要求 Validation Requirements of Risk Management Activities

6.1 风险管理计划是否已适当实施的验证

Validate whether the risk management plan is implemented appropriately.

评审组成员负责对风险管理计划的实施情况进行验证，以查看风险管理文档的方式查看风险分析、风险评价、风险控制等记录，确保风险管理计划策划的风险管理活动已得到适当的实施。

The members of evaluation group shall be responsible for validating the implementation of risk management plan to check records of risk analysis, risk evaluation, risk control and the like by means of checking the risk management file, so as to ensure risk management activity of risk management plan has been implemented appropriately.

6.2 风险管理活动效果的验证 Validation for effect of risk management activities

评审组可通过收集临床资料及生产和生产后信息对风险管理实施效果进行验证以确保风险管理活动的有效性。

Evaluation group shall validate implementation effect of risk management plan by means of collecting clinical data and the production & post-production information to ensure validity of risk management activities.

7、风险管理活动评审的要求 Review Requirements of Risk Management Activities

7.1 评审组成员及其职责如下 Members of evaluation group and their responsibilities are as follows:

姓名 **Name**	职位 **Position**	资质 **Competence**	在风险管理的职责 **Responsibilities in risk management**
Cao Mingtao	总经理 General Manager	外科手术器械行业资深专家，高级经济师,从事医疗器械制造与企业管理 30 多年，与时俱进的创新理念和宏观调配的大局观。 The senior expert in surgical equipment industry, senior economist, have engaged in medical device manufacturing and business management for more than 30 years, have the innovative ideas keeping pace with the times and the view of overall situation of macro-deploymen	项目负责人，制定风险评价准则;确保内部沟通，并进行风险评估 Project leader shall develop risk assessment criteria; ensure internal communication and perform risk assessment Project leader shall develop risk assessment criteria; ensure internal communication and perform 行风险评估 Project leader shall develop risk assessment criteria; ensure internal communication and perform risk assessment
Zhu Jianchun	技术总监 Technical Director	医疗器械专业工程师，熟悉行业的法规、从事医疗器械制造与管理近 30 年，具备 ISO13485 体系内审员 资质。 , professional engineers of medical devices, familiar with the industry regulations engaged in medical device manufacturing and management for nearly 30 years, , satisfying the ISO13485 system internal auditor qualifications.	从技术上确定可能存在制造缺陷，负责风险管理的实施，产品临床使用过程中的风险的识别，纠正、预防措施的制定与落实以及纠正措施的验证。 Technically sure possible manufacturing defect, be responsible for the implementation of risk management, risk identification in the process of product clinical use, formulate and implement corrective and preventive measures and validate corrective measures. 负责从法规、标准的角度对产品实现过程风险的评估和分析，并负责文件的整理 Be responsible for evaluating and analyzing risk in the product realization process from the perspective of laws and regulations, and sorting the documents.
Lu Jun	生产经理 Production Manager	机械制造专业工程师，熟悉行业的安全法规、从事医疗器械制造与管理近 30 年。 Professional engineers of mechanical manufacturing, familiar with the industry safety regulations, engaged in medical device manufacturing and management for nearly30 years.	从生产的角度来看估计故障发生的概率，评估器械状况严重程度、和制造过程中的风险识别及纠正预防。 Estimate the probability of failure occurrence from the perspective of production, as well as severity of equipment status, risk identification in the manufacturing process and corrective measures.
Zhu Xiaohuai	质量经理 Quality manager.	机械制造专业工程师，熟悉行业的安全法规、从事医疗器械制造与检测管理近 20 年，ISO13485 体系内审员。 Professional engineers of mechanical manufacturing, familiar with the industry safety regulations, engaged in medical device manufacturing and management for nearly 20years, the ISO13485 system internal auditor	产品实现的角度分析所有已知的和可预见的危害以及生产和生产后信息的收集并及时反馈给技术部进行风险评价，负责产品上市后的反馈及生产后信息的收集并及时反馈给技术部进行风险评价 Analyze all known and foreseeable harms from the perspective of product realization, collect production and post-production information and feed back the information to the Technology Development in time for risk evaluation, and in charge of the feed back of the product post marketing and collection of post-production information and feeding back to the Technology Development in time for risk evaluation.
Wan Guiping	医生 Doctor	从事妇产科临床工作近二十年，有丰富的妇产科理论知识及实践技能。熟练掌握妇产科各种疑难及高危病人的诊治及妇产科的各种手术操作。尤其擅长妊娠期糖尿病的诊断和治疗、遗传咨询及胎儿的产前诊断。拥有扎实的理论和实践经验 Engaged in the clinical work of gynaecology and obstetrics for nearly two decades, having profound theoretical knowledge of obstetrics and gynecology as well as practical skills. Skilled in the diagnosis and treatment of various complicated and high-risk patients of gynaecology and obstetrics as well as the surgical operations of gynaecology and obstetrics. Especially good at the diagnosis and treatment of gestational diabetes, genetic counselling and the prenatal diagnosis of the fetus. Have a solid theoretical and practical experience	从临床角度分析，临床获益和风险 Analyze clinical benefit and risk from a clinical perspective. assessment

7.2 评审组成员应对评审结果的正确性和有效性负责。

The members of the evaluation group shall be responsible for the correctness and validity of the evaluation results.

7.3 各部门应配合评审组成员利用《顾客投诉控制程序》及《产品忠告、召回控制程序》对与产品安全性有关的信息进行评审，为综合剩余风险的评价提供依据。

Various departments shall cooperate with the members of evaluation group to use *Processing Control Procedures of Customer Complaints* and *Issuing of Advisory Notice, Product Recall Control Procedures* to evaluate information related to the product safety, and provide the basis for comprehensive residual risk evaluation.

7.4 依据以下和安全性有关的信息在产品的设计开发、试制及产品生产与售后阶段进行评审：

Evaluation shall be carried out according to the following stages such as design development, pilot production, production and after-sales stages of product and information related to safety:

1）是否有事先未知的危害出现；

Whether there is previously unknown hazard;

2）是否有某项危害造成的已被估计的风险（一个或多个）不再是可接受的

Whether the estimated risk (one or more) caused by a certain hazard is non-acceptable

3）是否初始评定的其它方面已经失效；

Whether other aspects in the initial assessment have failed;

4）产品综合剩余风险是否已降低至可接受水平或经过风险/受益分析判断为可接受。

Whether the comprehensive residual risk of product is reduced to an acceptable level or judged as acceptable through risk/benefit analysis.

7.5 应对产品生产和生产后信息的获取方式进行评审

The way of acquiring product production and post-production information shall be evaluated.

保持评审记录以证实风险管理计划的每个要素在产品特定的生命周期阶段已被适当的实施。

Evaluation records shall be kept to prove that each element of the risk management plan has been implemented appropriately in the specific life cycle stage of the product.

8、综合剩余风险分析 Analysis of Comprehensive Residual Risk

8.1 在所有风险控制措施已经实施并验证后，各部门应考虑是否所有由 无菌手术刀片及塑柄手术刀造成的综合剩余风险依据本计划中第 4 条的准则判断是可接受的，如果判断为不可接受，则各部门应收集和评审有关资料和文献，以便决定预期用途的医疗受益是否超过综合剩余风险，如果上述证据支持医疗受益超过综合剩余风险的结论，则综合剩余风险是可接受的，否则综合剩余风险仍然是不可接受的。

After all risk control measures have been implemented and validated, various departments shall consider whether all comprehensive residual risks caused by Sterile surgical blades & scalpels with plastic handle are judged as acceptable according to criterion in the Article 4 of this plan. If the risk is judged as non-acceptable, various departments shall collect and evaluate the relevant data and documents to determine whether the intended use of the medical benefit is more than comprehensive residual risk, if the evidence supporting the medical benefit is more than comprehensive conclusion of residual risk, comprehensive residual risk is acceptable, otherwise comprehensive residual risk is stil non-acceptable.

8.2 各部门可以参考一下的一些方法评价综合剩余风险

Various departments shall refer to the following methods to evaluate the comprehensive residual risk.

1）事件树分析法：对单个风险进行共同研究，以便确定综合剩余风险是否可以接受；

Event tree analysis: performing the joint study on the individual risk to determine whether the comprehensive residual risk is acceptable;

2）故障树分析：同一种损害可能是由不同概率的危害处境造成的，该方法可以导出损害的结合概率；

Fault tree analysis: the same kind of harm may be caused by different probability of hazardous situation, the method can derive combination probability of harm;

3）对单个风险控制措施进行综合评审：对单个风险是适宜的风险控制措施可能产生相互矛盾的要求；

Carry out comprehensive evaluation for the individual risk control measures: if single risk is appropriate, conflicting requirements may be produced by control measures;

4）警告的评审：单个警告可能提供风险降低，但过多的警告可能降低警告的效果；

Warning evaluation: single warning may provide lower, but warning effect may be reduced in case of too much warning;

5）评审产品说明书：对无菌手术刀片及塑柄手术刀全部操作说明书的评审可能检出信息是不一致的，或者难以遵守的；

Evaluation of product manual: the information may be inconsistent through evaluation of product manual of Sterile surgical blades & scalpels with plastic handle or it is difficult to follow ;

6）比较风险：将整理过的单个剩余风险和类似现有的产品考虑不同使用情形下的风险进行逐个比较，尤其是最新的不良事件。

Risk comparison: compare single residual risk handled and the risks of similar current products in different use cases one by one, especially the latest adverse events.

8.3 各部门应决定哪些综合剩余风险应依据 ENISO14971-2012 附录 J 予以公布，应保持综合剩余风险的评价结果记录。

Various departments shall decide which comprehensive residual risk shall be released according to Annex J of ENISO14971-2012, evaluation result records of comprehensive residual risk shall be maintained.

9.残余风险分析 **Remaining Risk Analysis**

对无菌手术刀片及塑柄手术刀残余风险的评价，风险管理小组依据风险管理计划的第 4 条评价准则进行，实际上并不是所有控制措施都能完全消除风险,产品的整个生命周期内零风险是不存在。如果残余风险没有降低到可接受的级别，则必须重复风险管理过程，以找出一个将残余风险降低到可接受级别的方法。风险小组在对无菌手术刀片及塑柄手术刀的整个风险管理活动进行了充分的风险评估后，残余风险应在以下几个方面进行判定：

Evaluation of the remaining risk of Sterile surgical blades & scalpels with plastic handle, the risk management team is based on the evaluation criteria of Article 4 of the risk management plan. In fact, not all control measures can completely eliminate the risk, and the zero risk of the product is not present throughout the life cycle. If the remaining risk is not reduced to an acceptable level, the risk management process must be repeated to find a way to reduce the remaining risk to an acceptable level. The risk management team should determine the remaining risk after a full risk assessment of the entire risk management activity for Sterile surgical blades & scalpels with plastic handle:

(1)有意识接受的风险；

(1)Risks accepted consciously;

(2)已识别但误判断的风险；

(2)The identified but misjudged risks;

(3)未识别风险。

(3)Unrecognized risk.

残余风险识别的评价贯穿整个产品的生命周期，保持残余风险评价记录结果，纳入产品的风险管理文档。

The evaluation of remaining risk identification throughout the product life cycle, to maintain the assessment's records of remaining risk, and give them into the product risk management documents.

10、风险管理报告 **Risk Management Report**

在产品商业销售前，各部门应配合技术部完成对风险管理过程的评审，评审要求见本计划第 7 条，评审的结果最终以风险管理报告的方式给出。

Before commercial sales of the product, various departments shall cooperate with Technology Department to complete the evaluation of the risk management process. See Article 7 of the plan for the evaluation requirements. Final evaluation results shall be given in the form of risk management report.

第二章、风险分析和评价、控制记录

Chapter 2. Risk Analysis, Evaluation and Control Records

编制 Prepared by:：

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批准 Approved by：

风险分析和评价、控制记录

Risk Analysis, Evaluation and Control Records

1、 概述 Overview

1.1 风险分析 Risk analysis:

本次风险分析就是对该产品从生物危害、化学危害、信息危害、使用危害、功能失效等方面进行的已知和可预见的危害事件的一种初始危害分析，另外运用风险分析工具：FMEA、FMECA 和 HACCP 对无菌手术刀片及塑柄手术刀在生产阶段进行了分析包括危害分析和风险控制方案分析。

The risk analysis is just an initial hazard analysis for known and foreseeable harms in the aspects of biological hazard, chemical hazard, and information hazard, use hazard, function failure and the like. In addition, risk analysis tools such as FMEA, FMECA and HACCP are used for analyzing Sterile surgical blades & scalpels with plastic handle in the production stage, including hazard analysis and risk control scheme analysis.

1.2 风险评价：按照风险管理过程，对经风险分析确定的危害和危害处境发生的概率及其所引起的损害概率与损害的严重程度进行分析和评价。风险评价过程就是对经估计的风险与风险管理计划中给定的风险可接受准则进行比较，以决定该风险的可接受性。

Risk evaluation: according to the risk management process, hazard determined through risk analysis, occurrence probability of hazardous situation, caused harm probability and the severity of harm shall be analyzed and evaluated. Risk evaluation process is to compare acceptable Criteria of estimated risk and risks given in the risk management plan to determine the acceptability of the risk.

1.3 风险控制是对经过风险评价判断为不可接受的采取措施以降至可为接受风险的过程。

Risk control is a process of taking measures to reduce the risks judged as non-acceptable through risk evaluation to the acceptable risk.

2、风险分析、评价和控制人员 Risk Analysis, Evaluation and Control Personnel

按照风险管理计划的安排，此次分析、评价和控制的部门包括生产部、质管部、体系办公室、技术部、临床经理、销售部等。

According to the arrangement of the risk management plan, departments involved in analysis, evaluation and control include Production Department, Quality Department, system Office, Technology Department, Clinical Management Department, Sales Department, etc.

技术部主要分析、评价在设计开发阶段已知和可预见的危害事件序列，并对其风险提出控制措施：

Technology Development is mainly responsible for analyzing the known and foreseeab sequence of hazard events in the design development stage, and putting forward control measures for the risk;
生产部主要分析和评价产品生产阶段的已知和可预见的危害，并针对风险实施纠正预防；

Production Department is mainly responsible for analyzing and evaluating the known and foreseeable hazards in the production stage of product and take corrective and preventive measures for the risk;

临床经理、销售部主要分析产品生产后和临床使用方面已知和可预见的危害事件收集，并反馈给技术部；

Clinical Management Department and Sales Department are mainly responsible for collecting the known and foreseeable hazard events in the aspects of product post-production and clinical use, and feeding back them to Technology Department;

企业管理部负责产品实现过程和上市后法规、标准的可行性判定；

Enterprise management department is responsible for judging feasibility of laws, regulations and standards in the product realization process and after the product is listed;

质管部负责收集各部门分析的结果并按照 ENISO14971-2012 附录 E.1 的资料对所有已知和可预见的危害事件序列进行分类；

Quality Department is responsible for collecting results analyzed by various departments and classifying the known and foreseeable sequence of hazard events according to the data in Annex E.1 of ENISO14971-2012.

管理者代表组织个部门进行风险评价和风险控制措施的分析与实施并编制成相应文件。

Management representative shall organize various departments to carry out risk evaluation and analysis of risk control measurements and prepare corresponding document.

3、医疗器械预期用途与安全性有关特征的分析和判断 **Intended Use of Medical Device, Analysis and Judgement of Characteristics Related to Safety**

风险分析人员按照计划的要求和标准 ENISO14971-2012 附录 C 的资料，根据各自有关的专业和经验对预期用途和与安全性有关的特征进行了判断，同时对已知和可预见的危害进行了分析，记录如下：

Risk analysis personnel judge the intended use and characteristics related to the safety according to the requirements of plan and the data in Annex C of ENISO14971-2012 and in accordance with the respective related discipline and experience, and analyze the known and foreseeable hazards. Records are as follows:

I. 确定可能影响医疗器械安全的特征

Characteristics of affecting safety of mechanical device shall be determined.

1. 该医疗器械的预期用途是什么？如何使用该医疗器械？

What's the intended use of this medical device? How to use this medical device?

无菌手术刀片及塑柄手术刀用于切割人体的软组织。适用于外科、妇科、妇产科、泌尿科、骨科、骨科、口腔等；装配在刀柄使用。

Sterile surgical blades & scalpels with plastic handle are applied to incision soft tissues of human body in the clinic. It can be applied to surgical incision in department of surgical, gynecology, obstetrics, urology, orthopedics, orthopedics, and stomatology. Sterile surgical blade &scalpels with plastic handle are assembled on the surgical knife handles for the surgeons to cut the soft tissues.

2. 该医疗器械是预期植入的吗？

Is the medical device implanted expectedly?

不是。无菌手术刀片及塑柄手术刀用于切割人体的软组织。适用于外科、妇科、妇产科、泌尿科、骨科、骨科、口腔等。无菌手术刀片及塑柄手术刀的选用应考虑到患者切割部位。

No. Sterile surgical blades & scalpels with plastic handle are applied to incision soft tissues of human body in the clinic. It can be applied to surgical incision in department of surgical, gynecology, obstetrics, urology, orthopedics, orthopedics, and stomatology For the selection of Sterile surgical blades & scalpels with plastic handle, the patient's part of the cut shall be considered.

3. 医疗器械是否预期与患者或其他人员接触？

Is medical device expected to be in contact with patient or other persons?

无菌手术刀片及塑柄手术刀短期接触产品，可能会与临床人员短暂接触。

Sterile surgical blades & scalpels with plastic handle belongs to short-term involved contact product and it may be contact with the clinical personnel for a short time.

4.在医疗器械中利用何种材料或组分、或与医疗器械共同使用或与其接触？

Which material or component is used in the medical device? Is it jointly used with the medical device? Is it contact with the medical device?

主要材料：碳钢或不锈钢。手持刀柄进行软组织的切割。手术刀片将接触患者组织或体液，无不良反应。

Main materials: carbon steel or stainless steel. Medical personnel carry a knife handle to incision soft tissues of human body in the clinic， Sterile surgical blades & scalpels with plastic handle will be contact with patient's tissue or body fluids, no bad reaction.

5.是否有能量给予患者或从患者身上获取？

Is there energy given to patients or acquired from patients?

否。无相关事项

No. No relevant matters

6.是否有物质提供给患者或从患者身上提取？

Is there material provided to patients or acquired from patients?

否。无相关事项

No. No relevant matters

7.医疗器械是否处理生物材料用于随后的再次使用、输液/血或移植？

Is the medical device used for dealing with biological materials for the subsequent use, blood transfusion/or transplant?

否。无相关事项

No. No relevant matters

8.医疗器械是否以无菌形式提供或预期由使用者灭菌，或用其他微生物学控制方法灭菌？

Is the medical device provided in the sterile form? Is the sterilization carried out by the user expectedly? Is the sterilization carried out by other microbiological control method?

是。该产品是一次性无菌医疗器械。无菌手术刀片及塑柄手术刀产品经过辐照灭菌，辐照灭菌过程经过验证确认。

Yes.The product is disposable sterile medical device. Sterile surgical blades & scalpels with plastic handle product goes through sterilization by gamma ray, and gamma ray sterilization process is confirmed through verification.

9.医疗器械是否预期由用户进行常规清洁和消毒？

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

否。无相关事项

No. No relevant matters

10.医疗器械是否预期改善患者的环境？

Is the medical device expected to improve patient's environment?

否。无相关事项

No. No relevant matters

11.医疗器械是否进行测量？

Is the medical device measured?

否。无相关事项

No. No relevant matters

12.医疗器械是否进行分析处理？

Is the medical device analyzed?

否。无相关事项

No. No relevant matters

13.医疗器械是否预期和其他医疗器械、医药或其他医疗技术联合使用？

Is the medical device expected and jointly used together with other medical devices, medical or other medical technologies?

否。无相关事项

No. No relevant matters

14.医疗器械是否有有害能量或物质输出？

Does the medical device have harmful energy or substances output?

否。无相关事项

No. No relevant matters

15.医疗器械是否对环境影响敏感

Is medical equipment sensitive to environmental impact?

无菌手术刀片及塑柄手术刀对运输和储存环境敏感。它需要储存在干燥通风的环境中。在运输途中，需要避光、避免高温和潮湿。

Sterile surgical blades & scalpels with plastic handle is sensitive to transportation and storage environment. It needs to be stored in dry and ventilated environment. In transit, it is necessary to avoid light, high temperature and humidity.

16.医疗器械是否影响环境？

Does the medical device affect the environment?

使用后的废弃物应规范处置，避免污染环境。

After use, wastes shall be disposed regularly to avoid environmental pollution.

17.医疗器械是否有基本的消耗品或附件？

Does the medical device have basic consumables or attachments?

否。无相关事项

No. No relevant matters

18.医疗器械是否需要维护和校准？

Does the medical device need to be maintained and calibrated?

否。无相关事项

No. No relevant matters

19.医疗器械是否有软件？

Does the medical device have software?

否。无相关事项

No. No relevant matters

20.医疗器械是否有严格的储存寿命？

Does the medical device have strict storage life?

当小包装完好无损并且运输和储存正常时，有效期为 5 年。当过期使用时，可能会导致一些性能不达标造成意外。

When small-sized packing is in good condition and the transportation & storage are normal, period of validity is five years. If expired product is used, some performances cannot reach the standard to cause accident.

21.医疗器械是否有延时或长期使用效应？

Does the medical device have delayed or long-term use effects?

否。

No.

22.医疗器械承受何种机械力？

Which mechanical force is stressed on the medical device?

当手术刀片切割患者组织时，有切割力；

When the surgical blades passes through the tissue of the patient, there is cutting force;

当刀片穿过患者组织时，有阻力；

When the surgical blades passes through the tissue of the patient, there is resistance;

23.什么决定医疗器械的寿命？

What determines the service life of medical device?

产品是否按要求运输和储存。当运输和储存环境改变时（影响产品的温度和湿度），外力可能会导致小包装的密封性能以及产品性能产生变化。这些变化会影响医疗器械的寿命。

Whether the product is transported and stored according to the requirements. When the transportation and storage environment changes (temperature and humidity affecting the product), external force may cause the knot-tying of small-sized packaging, and product performance changes. These changes will affect the service life of medical device.

24.医疗器械是否预期一次性使用？

Is the medical device expected to be disposable?

是的，禁止重复使用。

Yes, it shall not be used repeatedly.

25.医疗器械是否需要安全的退出运行或处置？

Does the medical device need to be stopped or disposed safely?

在使用后无菌手术刀片及塑柄手术刀不能丢弃。它必须集中储存在一个特别容器内，并运送至医疗废物处置站。禁止重复使用。

Sterile surgical blades & scalpels with plastic handle shall not be discarded after use. Sterile surgical blades & scalpels with plastic handle must be stored in a special vessel in centralized and transported to medical waste disposal station. They shall not be used repeatedly.

26.医疗器械的安装或使用是否要求专门的培训或专门的技能？

Is special training or special skill required for installation or use of the medical device?

产品的使用必须由受过认可专业培训并获得相应资质的临床医生操作。不存在安装程序。

The use of the product must be operated by clinical doctors who are approved, trained professionally and obtain the corresponding qualifications. There is no installation program.

27.如何提供安全使用信息？

How to provide safe use information?

安全使用信息将直接通过说明书传达给终端使用者，无需培训。产品将由终端使用者处理和使用。当达到预期产品寿命时，禁止使用。

Safe use information will be directly transmitted to the end user through the instructions, without training. The product will be handled and used by the end user. When reaching the desired life, the product shall not be used.

28.是否需要建立或引入新的制造过程？

Is it necessary to establish or introduce a new manufacturing process?

否。

No.

29.医疗器械的成功使用，是否关键取决于人为因素，例如用户界面？

Is the successful use of the medical device crucially depending on human factors such as user interface?

否。

No.

30.医疗器械是否使用警报系统？

Does the medical device need an alarm system?

否。

No.

31.医疗器械可能以什么方式被故意地误用？

Which way may cause mis-operation of medical device intentionally?

无视制造商的使用提议（说明书和标识）。

Ignore use proposal of the manufacturers (instructions and identification).

32.医疗器械是否保存对患者护理非常重要的数据？

Does the medical device save data which is very important for patient care?

否。

No.

33.医疗器械是否预期用为移动式或便携式？

Is the medical device used in mobile or portable type expectedly?

否。无相关事项

No. No relevant matters

34.医疗器械的使用是否依赖于基本性能？

Does the use of medical device depend on the basic performance?

是，本产品直接用于临床，对患者进行组织等切割，取决于产品的基本性能。

Yes, the product is directly used for clinical purpose for cutting the tissue of patients, so it depends on the basic performance.

4、危害的分析、评价和控制 Analysis, Evaluation and Control of Hazard

风险分析人员依据预期用途和特征判定的提示，正常和故障状态下已知和可预见的危害事件序列参考 ENISO14971.2012 附录 E.1 危害示例进行了分类，同时对可能发生的损害和初 步控制措施进行了分析/评价，记录如下表：

Risk analysis personnel refer to hazard example in Annex E.1 of ENISO14971.2012 to classify the known and foreseeable sequence of hazard events under normal and fault condition according to the intended use and prompt judged by the characteristics, and analyze/evaluate possible harm and primary control measures. Records are shown as the following table:

4.1 危害判断分析 **The hazard judgement analysis**

危险源 **Hazard Source**	编号 **No.**	可预见的事件序列 **Predictable sequence of events**	危险处境 **Dangerous situation**	可能发生的危害 **The possibility of harm**	风险程度判定 **Judgement of risk degree**		
					损害严重度 **Damage severity**	发生概率 **probability of occurrence**	风险水平 **Risk level**
生物和化学危害 **Biological and Chemical Hazards**	H1	辐照灭菌不彻底，或产品的使用环境不规范,操作不规范，导致产品污染 The sterilization is insufficient by Gamma ray or the use of the environment and the operation is not standardized will lead to the product's pollution	患者使用非安全性的 无菌手术刀片及塑柄手术刀 The patient used the non-safe Sterile surgical blades & scalpels with plastic handle	导致感染，可能导致永久性损伤及生命危害 Infection is caused, permanent lesion or lifethreatening hazard may be caused.	4	2	R2
	H2	组成产品的各原材料的毒性（如：碳钢或不锈钢等） The toxicity of the raw materials that make up the product (eg, carbon steel, stainless steel, inner packing material, etc.)	患者接触到还原性物质 The patient touched the reductive substance	患者机体发热，严重时导致死亡 The patient have a fever and death may be caused if it's serious.	4	2	R2
	H3	交叉或重复使用导致刀片污染 Cross use or reuse may be caused the product's pollution	患者接触重复使用的或交叉使用的刀片 The patient touched the Sterile surgical blades & scalpels with plastic handle which is cross use or reuse	可能产生感染，可能导致永久性损伤及生命危害 Infection is caused, permanent lesion or lifethreatening hazard may be caused	3	2	R2
	H4	使用包装破损或过期产品 Use the product which is damaged packaging or expired	患者使用非安全性产品 Patients use non-safety products	导致感染，严重时需要医疗手段的介入 Infection is caused and medical intervention is required if it's serious.	3	2	R2
操作危害 **Hazard of operation**	H5	操作者未经过专业技能培训 The operator has not been professionally trained	患者由未经专业技能培训的操作者实施手术 The patient is operated by an operator who has not been professionally trained	无法完成手术或导致患者产生伤害 Can not complete the operation or lead to the patient harm.	3	2	R2
	H6	非预期使用 Unexpected us	无法完成手术 Can not complete surgery.	严重导致患者死亡 Death may be caused if it's serious.	4	2	R2
	H7	刀片切割过程中，刀片变形或断裂 The surgical blades body deformed or	患者的组织受到损伤，无法完成手术	可能会给患者身带来伤害，严重时需要医疗手段介入。	4	3	R2

		fractured in the punctured process.	The patient's tissue is damaged and surgery can not be complete	Leading to the patient harm and medical intervention is required if it's serious.			
	H8	刀片锋利度不够，无法完成组织切割 Surgical blades sharpness is not enough, can not complete the organization cutting.	无法完成手术 Surgery can not be completed.	手术时间延长 prolong the operation time	2	3	R2
	H9	刀片锈迹，无法使用 Surgical blades body rust and can not be used.	患者接触非安全性产品 Patients are exposed to non-safety products	可能引起感染 Infection is caused	3	2	R2
	H10	在实施组织切割时，刀片断裂或刀片脱落。 Surgical blades broken or surgical blades fell off in the process of stitching tissue.	无法完成手术 Surgery can not be completed.	可能会给患者身体带来损伤，延长手术时间 May cause damage to the patient's body, prolong the operation time	3	3	R2
信息危害 **Hazard of information**	H11	产品上标识不明确、不清晰或不准确（如：不得重复灭菌、不得重复使用，包装破损不得使用，产品效期等）The product's identification is unclear or inaccurate(Such as: no re-sterilization, no re-use, packaging damage shall not be used, the product's validity, etc.)	临床操作者无法预期正确使用产品 The clinical operator can not expect the proper use of the product	导致手术失败、或患者感染，严重时需医疗手段介入 Leading to surgical failure, or patient infection, medical intervention is required if it's serious.	3	2	R2...
	H12	说明书中关于安全警告、禁忌、注意事项的说明不充分 It's not sufficient for safety warnings, contraindications and precautions in the instruction.	临床操作者无法预期正确使用产品 The clinical operator can not expect the proper use of the product	导致手术失败、或患者感染，严重时需要医疗手段介入 Leading to surgical failure, or patient infection, medical intervention is required if it's serious.	3	2	R2
	H13	对于一次性产品重复使用导致的危险警告不足 There is not enough risk warning for repeated use of disposable products	患者重复使用或交叉使用 The patient touched the suture which is cross use or reuse	导致手术失败、或患者感染，严重时需要医疗手段介入 Leading to surgical failure, or patient infection,medical intervention is required if it's serious.	3	2	R2
	H14	使用后剩余刀片应规范处置 After use, the remaining Sterile surgical blades & scalpels with plastic handle should be standardized treatment	接触人员轻微伤害 The person who contacted the suture slightly hurt	处置不当，缝合针导致接触人员轻微伤害 Improper handling, the Sterile surgical blades & scalpels with plastic handle tip causes slight damage to the contact person	2	2	R1
	H15	使用后剩余刀片的处置 After use, the remaining Sterile surgical blades & scalpels with plastic handle should be treatment	导致环境污染 Leading to environmental pollution	导致环境污染 Leading to environmental pollution	1	2	R1
	H16	包装标识的防护信息缺失或不准确	患者接触非安全产品	患者感染，严重时需要医疗手段介入	3	2	R2

		The protective information of the packaging logo is missing or inaccurate	Patients are exposed to non-safety products	Leading to the patient's infection, and medical intervention is required if it'sserious.			
环境危害 **Environmental Hazard**	H17	产品使用效期内，包装老化 The packaging was aging during product validity period	患者使用的产品带菌 The product which is used by the patient carry bacteria	患者感染，严重时需要医疗手段介入 Leading to the patient' s infection, and medical intervention is required if it's serious.	3	2	R2
	H18	产品效期内性能下降（如生锈） Product performance declined during the validity period (such as rust etc)	患者使用性能有缺陷的产品 Defective products were used by the patients	无法完成手术，手术失败，或严重时导致永久性伤害 Can not complete surgery, surgery failed, or may cause permanent injury if it's serious	4	2	R2

4.2 采取措施后的危害判定分析 **Analysis to hazard judgement after taking measures**

危险源 **Hazard Source**	编号 **No**	可预见的事件序列 **Predictable sequence of events**	风险控制措施 **Risk control measures**			证明性文件 **Certification of document**	采取措施后的风险程度判定		
			固有的安全设计 **Inherent safety**	防护措施 **Protective measures**	安全信息 **Security Information**		损害严重度	损害发生概率	风险水平
生物和化学危害 **Biological and Chemical Hazards**	H1	辐照 灭菌不彻底，或产品的使用环境不规范；操作不规范，导致产品污染 The sterilization is insufficient by Gamma ray or the use of the environment and the operation is not standardized will lead to the product' s pollution	1.确认产品无菌性保证水准（SAL）：10-6。产品为一次性无菌使用医疗器械， 2.产品使用前密封包装。 1. Confirm product sterility assurance level (SAL): 10-6. The product is a disposable sterile use of medical instrument 2. The product should be sealed	1.在产品出厂箱上使用灭菌指示标签。 2.辐照 灭菌工艺的验证确认。 3.无菌检测作为产品出厂检验的项目之一. 1. The label which is sterile instructions should be on finished products 2.Gamma ray sterilization process validation is confirmed. 3. Aseptic testing is one of the products factory inspections.	1.标签信息“无菌”字样 2.标签和说明书明确“包装破损不得使用”字样；操作人员必须经专业技能培训。 1. The label information is "sterile" 2. Labels and instructions indicate clearly"packaging damage shall not be used" ; the operators must be professional skills training.	I. See—Section6 Products Sterilization **2.**. See- Section9 Product labeling control procedures **3**.See-Section15Manual of surgical blade &scalpes with plastic handle	4	1	R1
	H2	组成产品的各原材料有毒性（如：碳钢或不锈钢、内层包装材料等） The toxicity of the raw materials that make up the product (eg, carbon steel, stainless steel, imner packing material, etc.)	设计开发阶段确认使用生物性能符合ISO10993要求的材料 Used the biological properties of the material should be accordance with ISO10993 in the course of design and development	1.依据 ISO10993.1 的要求对缝线原材料和针体原材料实施生物学检测. 2.选择合格的供方。 1. According to th e requirements of ISO10993.1 suture and needle body ' s raw materials carry out biological testing. Select a qualified supplier.	生物学评价报告 biological evaluation report	**1.** See -- Section7Biological Compatibility **2.** See- Section4 Product spec & drawing	4	1	R1
	H3	交叉或重复使用导致刀片污染 Cross use or reuse may be caused the product' s pollution	说明书、标签的设计 Design of the instruction and label	标签和说明书提出警示。 Warning in the labels and instructions	标签和说明书明确“不可重复使用”图示和文字说明，说明书明确重复和交叉使用的不良后果警示 Labels and instructions put forward clearly by marKand description"non-reusable" ,make the warning about adverse consequence of re-use and cross	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic	3	1	R1

					use in the instructions	handle			
	H4	使用包装破损或过 期产品 Use the product which is damaged packaging or expired	说明书、标签的设计 Design of the instruction and label	标签和说明书提出警示。 Warning in the labels and instructions	标签和说明书明确“包装 破损不得使用”图示和文 字说明，产品包装清晰显 示产品效期。 Labels and instructions put forward clearly by mark and description"packaging damage shall not be used" ,product packaging clearly shows the product validity.	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle	3	1	R1
操作危害	H5	操作者未经过专业技能培训 The operator has not been professionally trained	说明书的设计 Design of the instruction	说明书提出警示。 Warning in the instructions	说明书明确产品的使用者必须是“经过专业技能培 训“剩余缝线应规范处置”的文字描述 Labels and instructions put forward clearly by mark and description"after the professional skills training" “the remaining suture should be standardized disposal	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle	3	1	R1
	H6	非预期使用 Unexpected use	说明书设计 Design of the instruction	说明书明确产品的预期用 途 The specification clarifies the intended use of the product	说明书文字描述产品的预期用途：于软组织缝合和（或）结扎，不用于心 血管组织和神经组织” Describe the intended useof the product "for soft tissue suture and / or ligation, not for cardiovascular tissue and nerve tissue"	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle	4	1	R1
	H7	刀片在切割过程中，刀片变形或断裂 Thesurgical blades body deformed or fractured in the cutting process.	选用合格牌号的医用碳钢或不锈钢 Select qualified grades of carbon steel or stainless steel	1.材料检测 2.产品制造过程中，刀片热处理的参数确认 3.成品的性能检测 4.选用适用规格的刀片 5.使用人员的规范操作，避免手术等器械损伤刀片。 1. Materia inspection 2. In the process of product manufacturing, the parameters of surbical blades heat treatment are confirmed. 3. Performance testing of finished product 4. Use the appropriate size of the surgical blades andthread,	说明书中明确： 1.根据临床的需要选择合适规格的刀片 2.产品的使用人员“经过专业技能培训” Indicate in the instructions: 1. the choice of the surgical blades should be in line with the clinical needs 2. Product users should be through professional skills training	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle **3**.See-Section4 Product spec & drawing	4	2	R2

				5.Regulate the operation by the user, to avoid the damage of the surgical blades body clamp,surgical scissors and other equipment damage					
	H8	在实施组织切割时， 刀片断裂或脱落。Thesurgical blades broken or Surgical blades fell off when cutting the tissue	选用合格的刀片。 Select the surgical blades which is qualified of the specification	1.刀片的弹性、韧性，刀片与刀柄的连接强度检测 The flexibility, toughness, blade and handle connection strength of the blade are tested	说明书中明确： 1.根据临床的需要选择合适规格的刀片 2.产品的使用人“过专业技能培训” Indicate in the instructions:1. According to the clinical application, select the appropriate specifications of the surgical blades 2. The user of the product should be through professional skills training"	**1..** See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle	2	2	R1
	H9	刀片锋利度不够，无法完成组织切割 Surgical blades sharpness is not enough, can not complete the organization cutting.	产品技术要求 Product technical requirements	规范刀片锋利度的过程检测，成品最终检测。 Standard the process testing Ofsurgical blades’ s sharpness and the final product testing.	产品技术要求中确定锋利度参数 Technical requirements to determine the sharpness parameters	See --Section1 Product introduction & classification	3	1	R1
	H10	刀片锈迹，无法使用 Surgical blades body rust and can not be used.	选择合格的牌号碳钢或不锈钢 Choose the carbon steel or stainless steel which is qualified trade mark	供方资质的确认储存，运输环境确认 Confirmation of supplier qualification,stomge and transportation environment	说明书中警示：刀片有锈迹，禁止使用 Instruction warnings: Not use if the surgical baldes body rust	**1..** See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle	3	2	R2
信息危害	H11	产品标识不明确、不清晰或不准确：（如：不得重复灭菌、不得重复使用、包装破损不得使用、产品效期等） The product’ s identification is unclear or inaccurate (Such as: no re-sterilization, no re-use, packaging damage shall not be used, the product’ s	依据ISO15223.1确定产品标识。 Determine the product identification according to ISO 15223.1.	产品包装标签图示、文字、符号、效期等信息的检测和确认 Mark,wordage, symbols and validity of the product detection and confirmation	说明书和标签信息的内容的符合性的确认 The confirmation of the contents of the instructions and labels	**1..** See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle	3	1	R1

		validity, etc.)							
	H12	说明书关于安全警 告、禁忌、注意事项 说明不充分 It's not sufficient for safety warnings, contraindications and precautions in the instruction.	说明书、标签设计 Design of the instruction and label	确认说明书中明确产品的 禁忌、警告和注意事项的描 述是否充分 Confirm the description of the product's contraindication, warning and cautions is sufficient	说明书充分显示中关于安 全警告、禁忌、注意事项 文字描述。 The instructions are fully displayed on the safety warning, contraindication and cautions	1.. See- Section9 Product labeling control procedures 2.See-Section15Manual of surgical blade &scalpes with plastic handle	3	1	R1
	H13	对于一次性产品重 复使用导致的危险 警告不足 There is not enough risk warning for re-use of disposable products	说明书、标签设计 Design of the instruction and label	标签说明书中图形和文字 的表示 The representation of mark and wordage in the instruction	1.产品标签明确“不得重 复使用”的符号 2.说明书中明确重复使用将导致：刀片断裂、污染、刀片与刀柄脱落等，术后可导致发热、感染等! 1. Indicate in the label of the product:"Do not re-use" 2. Indicate in the instructions: surgical blades break, dirt, connection of sargical blades and plastic handle break and for the patient more risks after surgery, can lead to fever, infection and so on	1.. See- Section9 Product labeling control procedures 2.See-Section15Manual of surgical blade &scalpes with plastic handle)	3	1	R1
	H14	包装标识的防护信 息缺失或不准确 The protective information of the packaging logo is missing or inaccurate	确认产品的储存、运输防护环境要求 Confirm the storage of the product, transport protection and environment requirements	1.产品标识和说明书明确 储存运输的标识和文字描 述。 2.包装运输验证确认 1. Indicate in the label and instruction:the transport logo and wordage description. 2.Packing and transport verification	产品的外包装和中盒包装 标识明确“避免阳光直 射”、“保持干燥”、“易碎， 小心操作”符号警示 Indicate in the mark of the product and medium box packaging "to avoid direct sunlight", "keep dry", "Fragile, Handle with care "	1.. See- Section9 Product labeling control procedures 2.See-Section15Manual of surgical blade &scalpes with plastic handle	2	1	R1
	H15	使用后剩余刀片应 规范处置 After use, the remaining surgical blades should be standardized treatment	说明书设计 Design of the instruction	产品说明书明确剩余刀片 规范处理要求 The product specification specifies standardize disposal requirements of the remaining surgical blades	说明书中对剩余刀片处置 描述：使用后的剩余刀片 应规范处置，防止刀片尖对 接触人员产生伤害 Indicate in the instruction : After use, the remaining Surgical blades	1.. See- Section9 Product labeling control procedures 2.See-Section15Manual of surgical blade &scalpes with plastic handle	1	1	R1

					should be standardized treatment to prevent the tip of the contact personnel to harm				
	H16	使用后剩余刀片使 用后处置 After use, the remaining surgical blades should be treatment	说明书设计 Design of the instruction	产品说明书明确剩余刀片 规范处理要求 The product specification specifies standardize disposal requirements of the remaining surgical blades	说明书中对剩余刀片处置 描述：使用后的剩余刀片 应规范处置，避免环境污 染 Indicate in the instruction:After use,the remaining surgical blades should be standardized disposal, to avoid environmental pollution	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle	3	1	R1
环境危害	H17	产品使用效期内，包 装老化 The packaging was aging during product validity period	确认产品的储存、运输防护环境要求 Confirm the storage of the product, transport protection and environment requirements	1.包装运输验证 2.产品的 3 年效期老化验证（分别验证 3 年和 5 年的效期老化试验） 1. Packing and transport verification 2. 3-year aging of the product (Validation of 3-year and 5-year aging tests, respectively)	1.标签和说明书明确“包 装破损不得使用”警示. 2.说明书明确产品的储存 条件：建议储存在湿度小 于 80%的清洁通风环境； 避免阳光直射或热源。 1. Indicate in the label and instruction "packaging damage shall not be used" 2.Indicate in the instruction: stored in a clean and ventilated environment with a humidity of less than 80%; avoid to direct sunlight or heat source.	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle 3.See-Section4 Product spec & drawing	3	1	R1
	H18	产品效期内性能下 降（如生锈） Product performance declined during the validity period (such as rust)	确认材料符合性 储存、运输防护环境的确认 Confirm the storage of the product, transport protection and environment requirements	1.进料检验 2.包装运输验证 3.产品的储存环境的确认 1. Incoming quality inspection 2. Packing and transport verification 3.Confirmation of the product’ s storage environment	说明书明确产品的储存条 件：建议储存在湿度小于 80%的清洁通风环境；避 免阳光直射或热源 Indicate in the instruction: stored in a clean and ventilated environment with a humidity of less than 80%; avoid to direct sunlight or heat source	**1.**. See- Section9 Product labeling control procedures **2**.See-Section15Manual of surgical blade &scalpes with plastic handle 3.See-Section4 Product spec & drawing	4	1	R1

5. 风险控制措施实施效果的验证 **Verification of effectiveness of risk control measures**

根据《风险管理计划》第 4 风险评价的准则，对风险控制措施实施效果验证记录如下：

According to the 4th item of *Risk Management Plan,* criteria for risk evaluation, verification record of the effect of risk control measures is as follows:

5 编号 Item	采取措施前风险评定 Precautionary risk evaluation			采取措施后风险评定 Post risk evaluation			是否产生新的风险 Whether generating new risks	验证结果 Verification results
	概率 Probability	严重度 Severity	风险水平 Risk level	概率 Probability	严重度 Severity	风险水平 Risk level	否 No	是否有效
H1	2	4	R2	1	4	R1	否 NO	有效 Effective
H2	2	4	R1	1	4	R1	否 NO	有效 Effective
H3	2	3	R2	1	3	R1	否 NO	有效 Effective
H4	2	3	R2	1	3	R1	否 NO	有效 Effective
H5	2	3	R2	1	3	R1	否 NO	有效 Effective
H6	2	4	R2	1	4	R1	否 NO	有效 Effective
H7	3	4	R2	2	4	R2	否 NO	有效 Effective
H8	3	2	R2	2	2	R1	否 NO	有效 Effective
H9	2	3	R2	1	3	R1	否 NO	有效 Effective
H10	3	3	R2	2	3	R2	否 NO	有效 Effective
H11	3	2	R2	1	3	R1	否 NO	有效 Effective
H12	3	2	R2	1	3	R1	否 NO	有效 Effective
H13	3	2	R2	1	3	R1	否 NO	有效 Effective
H14	2	2	R1	1	2	R1	否 NO	有效 Effective
H15	2	1	R1	1	1	R1	否 NO	有效 Effective
H16	2	3	R2	1	3	R1	否 NO	有效 Effective
H17	2	3	R2	1	3	R1	否 NO	有效 Effective
H18	2	4	R2	1	4	R1	否 NO	有效 Effective

根据上述比较，可总结出：

According to the above comparison, it can be concluded that

本产品采取了可靠的风险控制措施后，产品的风险得到很大的降低，可接受的风险中部分风险需要分析后接受，如概率为可忽略（10^{-6}），严重度为危重的（4），风险水平为 R1 ,从产品的风险的严重度来讲严重度为危重的（4），但是这种危害的发生概率为可忽略，自产品上市以来（近三年 3 亿片），无一例导致永久性损伤及生命的伤害事件，同时收集同类上市产品上市后的信息进行比对，也无不良事件发生。因此，该类风险定义为可接受风险。虽然还有的风险仍然可以尽可能降低，但考虑到产品的成本收益比值，我们认为基于受益和风险的角度分析，该产品的风险项在可接受的范围内。

After taking reliable risk control measures, the risk of the product is greatly reduced. Some of the acceptable risk need to be analyzed and accepted, for example, the probability is negligible (10^{-6}), the severity is critical (4), The risk level is R1, the severity of the risk of the product is critical (4), but the probability of the hazard is negligible. Since the product has been listed (nearly 300 million in the past three years), failure to cause permanent damage and damage to life, while collecting similar products listed on the market after the information comparison, and no adverse events. Therefore, this kind of risk is defined as an acceptable risk. While there are still risks that can be reduced as much as possible, taking into account the cost benefit ratio of the product, we think that the risk of the product is within an acceptable range based on the benefit and risk perspective.

第三章、综合剩余风险的可接受性评价

Chapter 3. Evaluation of Comprehensive Residual Risk

编制 Prepared by：

审核 Checked by：

批准 Approved by：

综合剩余风险评价

Evaluation of Comprehensive Residual Risk

1. 产品描述 Product Description:

无菌手术刀片及塑柄手术刀是采用碳钢或不锈钢制成的，适用于普通外科医生和专业切割外科医生。手术刀片的规格、硬度、锋利度、弹性、韧性及相关尺寸符合 YY0174 / YY0454 标准。

Sterile surgical blades & scalpels with plastic handle is made of stainless steel or carbon steel material which work in knife handle applied to the ordinary and professional incision surgeons .Sterile surgical blade specification ,hardness ,blade size and related handle size must meet the YY0174/YY0454 standards .Completed specification ,sharpness ,well elasticity and tenacity in our blade.

2. 概 述 **Overview**

综合剩余风险评价是以医疗器械安全、有效为宗旨在所有风险控制措施已实施并验证的情况下对无菌手术刀片及塑柄手术刀产品所有剩余风险可接受性的判断。

Comprehensive residual risk evaluation is the judgment on acceptability of all the residual risk of Sterile surgical blades & scalpels with plastic handle products with the purpose of safe and effective medical devices after the implementation and verification of all the risk control measures.

3. 生命周期的风险评价 **Risk evaluation in the life cycle**

按照本风险管理计划中确定的要求，对无菌手术刀片及塑柄手术刀产品在其整个生命周期内（设计开发、产品的制造、包装、运输、储存、最终停用和处置阶段）进行风险判定与措施和评估，依据第二章：风险分析和评价、控制记录中 4.1、4.2 中风险判定，确定风险管理活动覆盖整个产品的生命周期，汇总如下：

The Sterile surgical blades & scalpels with plastic handle product evaluated in terms of risk judgment and measures in its entire life cycle (design and development, product manufacturing, packaging, transportation, storage, final deactivated and disposal stages) pursuant to the requirements set out in this risk management plan, and determine the risk management activities to cover the product's whole life cycle in accordance with risk judgment of 5.1 and 5.2 in Chapter 2:risk analysis and evaluation, control records, with the summary as follows:

生命周期 Life Cycle	风险管理 Risk Management (第二章、风险分析和评价、控制记录中 4.1、4.2） (4.1 and 4.2 of Chapter II Risk Analysis, Evaluation and Control Records)	是否产生新的风险 Whether generating new risks	是否可接受 can be accepted
设计开发 Design and development	H1\H2\H3\H4H5\H6\H7\H8\H9\H11\H12\H14\H15\H17	暂未发现 Not found	可接受 Acceptable
产品制造 Product Manufacture	H1\H8\H9\H7\H10\H16	暂未发现 Not found	可接受 Acceptable
包装 Packaging	H1\H4\H5\H6\H7\H11\H12\H13\H14	暂未发现 Not found	可接受 Acceptable
储存、运输 Storage transportation	H14\H15\H16	暂未发现 Not found	可接受 Acceptable
最终停用和处置 Final deactivated and disposal stages	H4\H5\H6\H3\H12	暂未发现 Not found	可接受 Acceptable

4. 综合剩余风险可接受性评价

4.1 通过对无菌手术刀片及塑柄手术刀的风险判定和措施后的风险判定分析，所有的单个剩余风险是可接受的，同时对每个剩余风险均有控制措施，单个风险的控制措施没有相互矛盾， 各个危害/原因项的风险均被降低到可接受区域，其收益都大于风险，均被视为是可接受的。 评审警告语：警告语数量是适当的；评审说明书：说明书没有矛盾的地方，易遵守。

All individual residual risks are acceptable through the risk judgment as well as the risk judgment and analysis after taking measures of Sterile surgical blades & scalpels with plastic handle. In addition, control measures are imposed on each residual risk, and the control measures for individual risks are not contradictory. The risk of each hazard / cause item is reduced to an acceptable area, and the benefits are greater than risks and are considered as acceptable. The review warnings: the number of warnings is appropriate; the review instruction: no contradictions exist in the instruction, and it is easy to follow.

4.2 由风险评价、判定和控制记录来看，在所有风险控制措施实施之后没有带来新的风险，但是产品总的综合剩余风险可能存在如下：

Judging from the risk evaluation, decision and control records, there is no risk generated by all of the risk control measures, however，comprehensive residual risk may be possible as follows:

A）产品使用后如果处理不当，可能导致接触人员产生伤害（刀尖）或对环境造成一定的影响。

A）Improper disposal of used product may cause injury (tool nose) to personnel who contact it or cause certain influence on the environment.

这样的剩余风险概率无法估计，但经风险/受益分析，该产品带来的受益大于风险，另外，公司采取了确实可行的措施，尽可能的降低风险危害，如在产品产品的标签和使用说明书中做出明确的描述和提示，由此，决定该产品的综合剩余风险可接受。

The probability of such residual risk cannot be estimated. But after risk / benefit analysis, the benefits brought by the product are greater than risk. In addition, the company has taken some measures to minimize risk hazards, for instance, offer a clear description or hint in the instructions and labels of the product. Therefore,it is determined that the overall residual risk of the product is acceptable.

5、需公开的剩余风险信息 Residual risk information to be publicly disclosed

生产部、质管部、销售部、医生、技术部等经商讨，决定以产品说明书的形式公开如下剩余风险：

After the discussion of production department, quality department, sales department, doctor and technical department, the following residual risks are decided to be exposed in the form of product instruction:

A) 使用后的剩余无菌手术刀片及塑柄手术刀应规范处置，避免产生环境污染，防止刀尖对接触人员产生伤害。

The remaining Sterile surgical blades & scalpels with plastic handle after use shall be disposed properly to avoid environmental pollution, and prevent injury to personnel who contact it by the tool nose.

第四章、残余风险的可接受性评价

Chapter 4. Remaining risk acceptability evaluation

编制 Prepared by:：

审核 Checked by:

批准 Approved by：

残余风险的可接受性评价

Remaining risk acceptability evaluation

1. 概述 Overview

我们对产品整个生命周期（包括设计开发、产品的制造、包装、运输、储存、最终停用和处置阶段）实施了风险管理，通过风险措施，只是保证已识别的风险降低到可接水平。但是我们知道，不是所有安全控制都能完全消除风险。在产品的整个生命周期内可能还会存在未识别的或未知的风险，风险不可能彻底消除，零风险是不存在的，因此有一定的残余风险。

Risk management has been implemented in the whole life cycle of the product (including design and development, product manufacturing, packaging, transportation, storage, final decommissioning and disposal phases), and the risk measures are only to ensure the reduction of identified risks to an acceptable level. We shall aware that, however, not all safety controls can eliminate the risk completely. There may be unrecognized or unknown risks in the entire life cycle of the product. So there is certain residual risk as the risks cannot be eliminated completely and zero risk does not exist.

2. 残余风险的识别与评价 **Recognition and evaluation of remaining risk**

对无菌手术刀片及塑柄手术刀残余风险的评价，风险管理小组依据风险管理计划的第 4 条评价准则进行，若某些风险可能在选择了适当的控制措施后仍处于不可接受的风险范围内，考虑是否接受此类风险或增加更多的风险控制措施。为确保所选择的风险控制措是有效的，必要时可进行再评估，以判断实施风险控制措施后的残余风险是否降到了可接受的水平。风险管理小组在对无菌手术刀片及塑柄手术刀整个风险管理活动进行了回顾，确定残余风险包括以下三个部分：

The risk management team conducted evaluation of Sterile surgical blades & scalpels with plastic handle residual risk in accordance with Article 4 evaluation criteria of Risk Management Plan. If certain risks are likely to be in an unacceptable risk range after taking appropriate control measures, consider whether to accept such risks or if more risk control measures are needed. Reassessment may be performed to ensure the selected risk control measures to be effective, if necessary, so as to determine whether the residual risk has been reduced to an acceptable level after implementation of the risk control measures. The risk management team determines that the residual risks include the following three parts after reviewing the entire risk management activities of Sterile surgical blades & scalpels with plastic handle:

(1)有意识接受的风险；

(1) Risks accepted consciously;

(2)已识别但误判断的风险；

(2)The identified but misjudged risks;

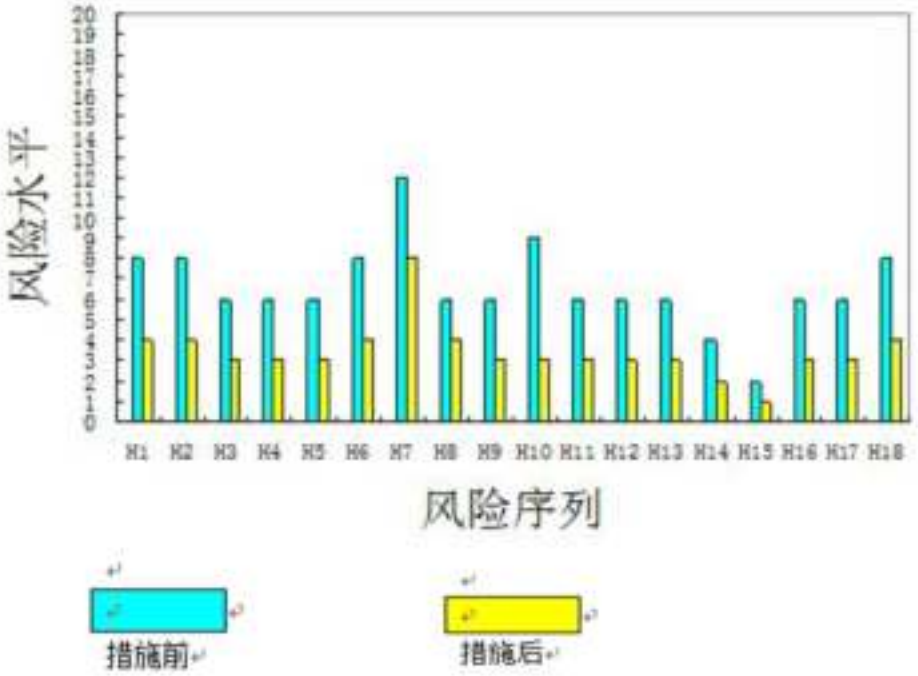
(3)未识别风险。

(3) Unrecognized risk.

2.1 对于有意识接受的风险，见第二章、风险分析和评价、控制记录（3.0 和 4.1 和 4.2），通过措施前后风险水平的对比，风险管理小组确定，措施后的风险得到有效控制，风险水平均在可接受区，大部分措施后的风险水平处于可忽略。未见残余风险。见下表;

As for the risks accepted consciously, see Chapter 2, Risk Analysis and Evaluation, Control Records (3.0 and 4.1 and 4.2). The risk management team determines through comparison of the risk levels before and after taking measures that, the risks are effectively controlled after taking measures. The risk levels are in the acceptable area, and most of the risk levels after taking measures are negligible. No residual risk found. See the following table:

风险水平对比表



2.2.对于已识别的风险（第二章、风险分析和评价、控制记录（3.0 和 4.1 和 4.2）），有效措施的验证，未见识别的风险中，未见判定错误的分析

2.2 For the identified risks, (Chapter 2, Risk Analysis and Evaluation, Control Records (3.0 and 4.1and 4.2)), effective measures validated that no identified risk found, no misjudged analysis 2.3. 目前未发现未识别的风险。

2.3.No unidentified risks found currently.

3. 结论 **Conclusion**

风险管理小组对 无菌手术刀片及塑柄手术刀的单个风险和剩余风险、临床运用的反馈、生产和生产后信息进行了充分的评估后，确定有意识接受的风险已得到识别，已识别的风险没

有判定错误，暂未发现未识别的风险。因此，风险管理小组确定无菌手术刀片及塑柄手术刀风险管理活动中无残余风险。或许我们对无菌手术刀片及塑柄手术刀的风险识别和评估可能存在遗漏或不足，我们会持续不间断的收集相-关的信息和数据，尽可能的充分识别残余风险，并实施纠正预防，对产品的风险实施动态管理。

The risk management team determines after sufficient evaluation of the suture ' s individual risks and residual risks, the feedback of clinical use, the production and post-production information that, the risks accepted consciously have been identified, the identified risks are not misjudged and no unrecognized risk found. Therefore, the risk management team determines that there is no residual risk in Absorbable suture risk management activities. Perhaps there may be deficiencies in our risk identification and assessment of the cutting, we will continue to collect relevant information and data to fully identify the residual risk as far as possible, implement the corrective prevention measures, and manage the risks of products dynamically.

第五章、风险管理报告

Chapter 5. Risk management report

Surgical blades & Scalpels with Plastic Handle

Model:18#,19#,20#,21#,22#,23#,24#, 25#,26#,27#,34#,36#27#22A#9#,10#, 11#,12#,13#,14#,15#,16#6#10A#12B# 12D#15A#

编制 Prepared by:

审核 Checked by:

批准 Approved by:

日期 Date:
2017-12-10

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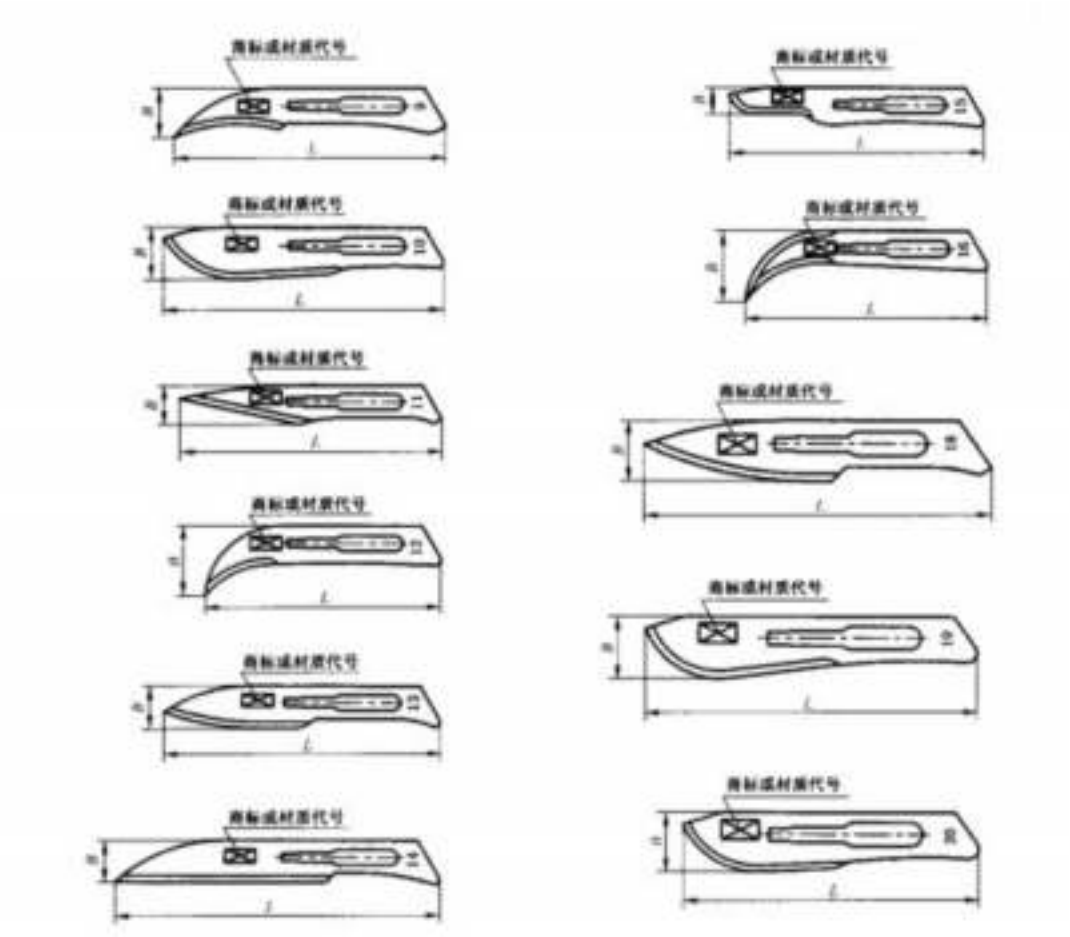
第一章 综 述

Chapter 1 Review

1. 产品介绍 Product Introductions

产品描述 Product Description:

无菌手术刀片及塑柄手术刀是采用碳钢或不锈钢制成的，适用于普通外科医生和专业切割外科医生。手术刀片的规格、硬度、锋利度、弹性、韧性及相关尺寸符合 YY0174 / YY0454 标准。Sterile surgical blades & scalpels with plastic handle is made of stainless steel or carbon steel material which work in knife handle applied to the ordinary and professional incision surgeons .Sterile surgical blade specification ,hardness ,blade size and related handle size must meet the YY0174/YY0454 standards .Completed specification ,sharpness ,well elasticity and tenacity in our blade.



2. 风险管理计划和实施情况简述

Brief description of risk management plan and implementation

于 2007 年开始策划立项。立项的同时。我们针对无菌手术刀片及塑柄手术刀产品进行了风险管理活动的策划，制定了风险管理计划。

It is planned and initiated in 2007. When initiating, We made risk management plan for Sterile surgical blades & scalpels with plastic handle.

该风险管理计划确定了的风险可接受准则，对产品设计开发阶段（包括试生产阶段）的风险管理活动、风险管理活动有关人员的职责和权限以及生产和生产后信息的获得方法的评审要求进行了安排。

The acceptable criterion of risk determined by risk management plan allocates the risk management activities, relevant personnel responsibilities and authorities as well as the method to collect production and post-production information in product design and development stage (including trial production stage).

公司组成了风险管理小组，确定了该项目的风险管理负责人。确保该项目的风险管理活动按照风险管理计划有效的执行。

The company formed a risk management team and decided the risk management director of this project. Make sure that the risk management activities of this project is effectively implemented in accordance with the risk management plan.

在产品的设计和项目开发阶段，风险管理小组共进行了一次风险管理评审，形成了相关的风险管理文档。

During the design and development stage of the product, the risk management team conducted one risk management review and formed related risk management document.

3. 风险管理评审目的 **Purpose of risk management review**

本次风险管理的评审目的是通过对产品在上市前各阶段风险管理活动进行总体评价，确保风险管理计划已经圆满地完成，并且通过对该产品的风险分析、风险评价和风险控制，以及综合剩余风险的可接受性评价，和对生产和生产后信息获得方法的评审，证实对产品的风险已进行了有效管理，并且控制在可接受范围内。

The review purpose of risk management is by overall evaluation of risk management activities in different stages before the launching of the product to ensure that risk management plan has been completed successfully, and through the risk analysis, evaluation and control of the product, the evaluation of comprehensive residual risk , and the review of method to collect production and post-production information to confirm that the product risk has been managed effectively and controlled within an acceptable range.

4. 风险管理评审小组成员及其职责

Members of risk management review team and their responsibilities

姓名 **Name**	职位 **Position**	资质 **Competence**	在风险管理的职责 **Responsibilities in risk management**
Cao Mingtuo	总经理 General Manager	外科手术器械行业资深专家，高级经济师,从事医疗器械制造与企业管理 30 多年，与时俱进的创新理念和宏观调配的大局观。 The senior expert in surgical equipment industry, senior economist, have engaged in medical device manufacturing and business management for more than 30 years, have the innovative ideas keeping pace with the times and the view of overall situation of macro-deploymen	项目负责人，制定风险评价准则;确保内部沟通，并进行风险评估 Project leader shall develop risk assessment criteria; ensure internal communication and perform risk assessment Project leader shall develop risk assessment criteria; ensure internal communication and perform 行风险评估 Project leader shall develop risk assessment criteria; ensure internal communication and perform risk assessment
Zhu Jianchun	技术总监 Technical Director	医疗器械专业工程师，熟悉行业的法规、从事医疗器械制造与管理近 30 年，具备 ISO13485 体系内审员 资质。 , professional engineers of medical devices, familiar with the industry regulations engaged in medical device manufacturing and management for nearly 30 years, , satisfying the ISO13485 system internal auditor qualifications.	从技术上确定可能存在制造缺陷，负责风险管理的实施、产品临床使用过程中的风险的识别，纠正、预防措施的制定与落实以及纠正措施的验证。 Technically sure possible manufacturing defect, be responsible for the implementation of risk management, risk identification in the process of product clinical use, formulate and implement corrective and preventive measures and validate corrective measures. 负责从法规，标准的角度对产品实现过程风险的评估和分析，并负责文件的整理 Be responsible for evaluating and analyzing risk in the product realization process from the perspective of laws and regulations, and sorting the documents.
Lu Jun	生产经理 Production Manager	机械制造专业工程师，熟悉行业的安全法规、从事医疗器械制造与管理近 30 年。 Professional engineers of mechanical manufacturing, familiar with the industry safety regulations, engaged in medical device manufacturing and management for nearly30 years.	从生产的角度来看估计故障发生的概率，评估器械状况严重程度、和制造过程中的风险识别及纠正预防。 Estimate the probability of failure occurrence from the perspective of production, as well as severity of equipment status, risk identification in the manufacturing process and corrective measures.
Zhu Xiaohuai	质量经理 Quality manager.	机械制造专业工程师，熟悉行业的安全法规、从事医疗器械制造与检测管理近 20 年，ISO13485 体系内审员。 Professional engineers of mechanical manufacturing, familiar with the industry safety regulations, engaged in medical device manufacturing and management for nearly 20years, the ISO13485 system internal auditor	产品实现的角度分析所有已知的和可预见的危害以及生产和生产后信息的收集并及时反馈给技术部进行风险评价，负责产品上市后的反馈及生产后信息的收集并及时反馈给技术部进行风险评价 Analyze all known and foreseeable harms from the perspective of product realization, collect production and post-production information and feed back the information to the Technology Development in time for risk evaluation, and in charge of the feed back of the product post marketing and collection of post-production information and feeding back to the Technology Development in time for risk evaluation.
Wan Guiping	医生 Doctor	从事妇产科临床工作近二十年，有丰富的妇产科理论知识及实践技能。熟练掌握妇产科各种疑难及高危病人的诊治及妇产科的各种手术操作。尤其擅长妊娠期糖尿病的诊断和治疗，遗传咨询及胎儿的产前诊断。拥有扎实的理论和实践经验 Engaged in the clinical work of gynaecology and obstetrics for nearly two decades, having profound theoretical knowledge of obstetrics and gynecology as well as practical skills. Skilled in the diagnosis and treatment of various complicated and high-risk patients of gynaecology and obstetrics as well as the surgical operations of gynaecology and obstetrics. Especially good at the diagnosis and treatment of gestational diabetes, genetic counselling and the prenatal diagnosis of the fetus. Have a solid theoretical and practical experience	从临床角度分析，临床获益和风险 Analyze clinical benefit and risk from a clinical perspective. assessment

第二章 风险管理评审输入

Chapter 2 Review Input of Risk Management

1.可接受风险标准 Criteria for Acceptable Risk

风险管理小组根据《风险管理控制程序》中所定义的指导原则评估风险/可接受风险标准，并认为无菌手术刀片及塑柄手术刀的剩余风险是可接受的。

According to the guiding principle defined in the *Risk Management and Control Procedures*, the risk management team assess risk/acceptable risk and affirm that the residual risk of Sterile surgical blades & scalpels with plastic handle is acceptable.

1.1. 严重度定性 4 级 Determination of Severity Grade 4

等级 **Ratings**	代号 **Code**	系统风险定义 **System risk definition**
危重	4	导致永久性损伤或生命的伤害 Cause permanent damage and damage to life 示例说明： **Description:** 比如手术过程中刀片断裂，导致断刀片留在组织内，需要一些医疗手段的及时处理，严重可能导致某些组织永久性损伤或严重导致生命伤害 For example, the surgical blades breaks in the course of surgery and leaves the broken Surgical blades in the tissue, which requires the medical treatment timely, otherwise it may cause permanent damage to certain tissues or serious damage to life
严重	3	导致专业医疗介入的伤害或损伤 Cause injury or damage requiring professional medical intervention 示例说明： **Description:** 重复使用，可能导致感染、发热等，需介入医疗手段（使用抗感染药物等） Reuse of it may cause infection, fever and so on, requiring medical treatment intervention (use anti-infective drugs etc.)
轻度	2	导致不要求专业医疗介入的暂时伤害或损伤 Cause temporary injury or damage that does not require professional medical intervention 示例说明： **Description:** 使用后剩余的手术刀片应规范处置，刀尖导致接触人员产生轻微损伤，暂时伤害或损伤，一般无需医疗介入。

		The remaining surgical blades after use shall be disposed properly, and the surgical blades tip may cause slight damage, temporary injury or damage, to the personnel who contact it, generally it requires no medical intervention.
可忽略	1	不便或暂时不适； Inconvenient or temporary discomfort; 示例说明： **Example Description:** 使用后的剩余手术刀片，应规范处置，可能导致环境污染。 The remaining surgical blades after use shall be disposed properly or it may cause environmental pollution.

1.2 损害发生概率的估计 Estimation of occurrence probability of damage

等级 Ratings	代号 Code	频次（每年）Frequency (per year)
经常 Usual	5	$\geq 10^{-3}$
有时 Sometimes	4	$<10^{-3}$ 和$\geq 10^{-4}$
偶然 Incidental	3	$<10^{-4}$ 和$\geq 10^{-5}$
很少 Very little	2	$<10^{-5}$ 和$\geq 10^{-6}$
非常少 Rare	1	$<10^{-6}$

注：每片刀片及塑柄手术刀发生事件的次数或预期每年发生的次数{危害事件数/单位产品（年销售）}。

Note: Number of event occurrences of each Sterile surgical blades & scalpels with plastic handle or the expected number of occurrences each year (number of hazardous events/unit product (annual sales)).

示例说明：

Description:

2014 年、2015 年、2016 年 无菌手术刀片及塑柄手术刀年产量分别：41 万片、39 万、43 万，平均年产量 41 万。

The annual output of Sterile surgical blades & scalpels with plastic handle in 2014, 2015 and 2016 is 410,000 pieces, 390,000 and 430,000 respectively, with the average annual output of 410,000.

2014 年、2015 年、2016 年一共收集危害事件数*（如：刀片锋利度不合格）*：15 件 、8 件、7 件。

The number of hazardous events (eg. unqualified surgical blades sharpness) collected in 2014, 2015 and 2016 is 15, 8 and 7.

平均危害事件数为 10 件。

The average number of hazardous events is 10.

危害概率=危害事件数÷单位年产品=10 件÷41 万=1/41000 即在$<10^{-4}$ 和$\geq 10^{-5}$ 之间，发生概率代号 3，概率等级为偶然。

Hazard probability =number of hazardous events ÷unit annual output=10 pieces÷410,000 = 1/41000 namely between<10-4and≥10-5, the probability of occurrence code is 3, so the probability level is accidental.

1.3 风险评价准则 Risk evaluation standards

损害发生概率 Occurrence probability of damage		严重程度 Rank			
		4	3	2	1
		危重 Critical	严重 Severe	轻度 Mild	可忽略 Negligible
经常 Usual	5	R_3	R_2	R_2	R1
有时 Sometimes	4	R_3	R_2	R_2	R1
偶然 Incidental	3	R_2	R_2	R_2	R_1
很少 Very little	2	R_2	R_2	R_1	R_1
非常少 Rare	1	R_1	R_1	R_1	R_1

注：风险水平(R)=损害严重度╳概率

Note : Risk Level (R) = Damage severity ╳ Probability

R1(1-5)：可忽略的风险 R1(1-5): Negligible risk

R2(6-15): 可接受的风险（进一步减低风险的研究，如具有技术可行性，应实施风险控制措施）

R2 (6-15): Acceptable risk (study for further reduction of risk, risk control measures should be implemented if it is of technical feasibility)

R3(16-20)：不可接受的风险

R3 (16-20): unacceptable risk

2. 风险管理文档 **Risk Management File**

2.1 风险管理计划；

Risk management plan

2.2 安全性特征问题清单及可能危害分析记录；

Security features issue list and analysis record of possible hazard;

2.3 风险（剩余风险）分析和评价、控制记录；

Analysis, evaluation and control record of risk (residual risk);

2.4 生产和生产后信息收集文件.

File of production and post-production information collection

3. 相关文件 **Related documents**

3.1 风险管理控制程序　　文件编号：QP021

Risk management and control procedure No.: QP021

3.2 产品设计开发文档（主要包括设计图纸、工艺、DFMEA、PFMEA）

Product design and development document (including design drawings, process, DFMEA, PFMEA)

3.3 相关法规、协调标准如下：

Relevant laws, regulations and coordinate standards are as follows:

序列号 S/N	标准 Standard	名称 Designation
1	EN556-1:2001	医疗设备消毒.标有"消毒"字样医疗设备要求.第 1 部分:定期消毒医疗设备要求 Sterilizationofmedicaldevices-Requirementsformedicaldevicestobedesignated"STERILE"-Part1:Requirementsforterminallysterilizedmedicaldevices;
2	EN ISO14971:2012	医疗器械-对医疗器械的风险管理(ISO 14971:2012) Medical devices - Risk management for medical devices (ISO 14971:2012)
3	EN ISO 11607-1:2009	最终无菌医疗器械的包装- 第 1 部分：材料、无菌屏蔽系统和包装系统的要求 Packaging of ultimate sterile medical devices - part 1: requirements for materials, sterile shielding system and packaging system
4	EN ISO 11607-2:2006	最终无菌医疗器械的包装- 第 2 部分：成型、密封和装配过程的确认要求 Packaging of ultimate sterile medical devices - part 2: validation requirements for forming, sealing and assembly process
5	EN ISO 11737-1:2009	医疗器械灭菌- 微生物方法-第 1 部分：产品上微生物群落的确定 Sterilization of medical devices - microbiological methods - part 1: determination of microbial communities on products
6	EN ISO 11137-2:2009	医疗器械灭菌.微生物学方法.第 2 部分:灭菌过程的定义、有效性和维护中进行的无菌试验 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
7	ISO14155.1:2003	临床研究医疗设备-第 1 部分:一般要求 Clinical investigation of medical devices for human subjects—Part 1:General requirements
8	EN 1041:2008	厂商提供的医疗设备信息 标准信息 Information provided by medical device manufacturers
9	ENISO15223-1：2012	医疗设备 - 符号用于医疗器械标签，标记和被提供的信息 - 第 1 部分：一般要求 medical devices - symbols to be used with medical device labels, labelling and information to be supplied - part 1: general requirements
10	EN ISO10993-1:2009	医疗器械生物评价-第 1 部分：在风险管理过程中的评价和检测 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
11	EN ISO10993-3:2009	医疗器械生物评价-第 3 部分：基因毒性、致癌性和生殖毒性的检测 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
12	EN ISO10993-4:2009	医疗器械生物评价-第 4 部分：与血液相关检测的选择 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
13	EN ISO10993-5:2009	医疗器械生物评价-第 5 部分：体外细胞毒性的检测 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
14	EN ISO10993-6:2009	医疗器械生物评价-第 6 部分：植入后局部反应测试 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
15	EN ISO10993-9:2014	医疗器械生物评价-第 9 部分：潜在降解产物的量化和识别框架 Biological evaluation of medical devices Part 9 Framework for identification and quantification of potential degradation products
16	ISO10993-10:2010	医疗器械生物评价-第 10 部分：刺激性和迟发型过敏的检测 "Biological evaluation of medical device, part. 10: irritation and delayed-type hypersensitivity test
17	EN ISO 10993-11:2009	医疗器械生物评价-第 11 部分：全身毒性的检测 Biological evaluation of medical devices Part 11: Tests for systemic toxicity

第三章 风险管理评审

Chapter 3 Risk Management Review

1. 风险管理评审实施 **Implementation of risk management review**

RMRT（风险管理评审小组）已检查风险管理计划的执行，并对每份管理文档进行 RMRG 检查后判断手术刀片的风险管理计划已得到执行和实施。详细信息请见文档《风险管理计划小结》。

RMRT (risk management review team) have checked the implementation of risk management plan. After the RMRG check on each management document, it has determined that the risk management plan of Sterile surgical blades & scalpels with plastic handle has been implemented. Detailed information please see the document "risk management plan summary".

2. 综合剩余风险可被检查和评估 **Comprehensive residual risk can be checked and evaluated**

在考虑所有剩余风险的影响后，RMRT 综合分析了所有剩余风险并得出最终结论如下——产品的综合剩余风险是可接受的。以下特别指出五个评估点：

After considering influence of all the residual risk, RMRT conducted comprehensive analysis on all the residual risk and drew the following final conclusion - the comprehensive residual risk of the product is acceptable. Five evaluation points specifically noted in the following:

1) 在单个风险控制中是否有任何冲突要求？

Is there any conflicting requirement in individual risk control?

结论—— 在个别风险控制中无发现冲突。

Conclusion - conflict is not found in individual risk control.

2) 警告检查（包括是否警告过多）

Warning check (including whether there are excessive warnings)

结论—— 警告备注清晰并符合标准。

Conclusion - warning note shall be clear and conform to the standard.

3) 用户手册的检查（包括是否有冲突，是否难以遵守）

Check the user guidance (including whether there are conflicts or difficulties to comply with)

结论—— MDD 指令和产品安全标准的要求。产品安全的描述清晰且可以理解，易于阅读。

Conclusion - MDD instruction and requirements for product safety standards. The description of the product security is clear, understandable and easy to read.

4) 同类产品的比较 The comparison of similar products

结论—— 在与淮阴医疗器械有限公司生产的无菌手术刀片及塑柄手术刀进行临床对比，并对无菌手术刀片及塑柄手术刀的特性、功能进行分析后，我司的无菌手术刀片及塑柄手术刀在性能指标、功能和临床用途方面与上述品牌一致。

Conclusion - clinically compared with the Sterile surgical blades & scalpels with plastic handle produced by Huaiying Medical Instruments Co., LTD., and analyzed the characteristic and function of Sterile surgical blades & scalpels with plastic handle produced by Huaiying Medical Instruments Co., LTD., the Sterile surgical blades & scalpels with plastic handle of our company is in accordance with the above the brands in terms of performance index, function and clinical use.

5) 专家结论 Expert conclusion

结论—— 在分析上述所有情况并与临床专家进行深入仔细的沟通后，RMRT 认为产品的综合剩余风险是可接受的。

Conclusion - after the analysis of all the above situation and in-depth communication with clinical experts, RMRT considered that the comprehensive residual risk of this product is acceptable.

3. 残余风险的判定与评估 **Judgement and Assessment of Remaining Risk**

风险管理小组对无菌手术刀片及塑柄手术刀的单个风险和剩余风险、临床运用的反馈、生产和生产后信息进行了充分的评估后，确定：

The risk management team assessed the individual risks and residual risks of Sterile surgical blades & scalpels with plastic handle, feedback on clinical application, post-production and post-production information, and determined: 1.有意识接受的风险已得到识别；

The consciously acceptant risk has been dentified

2.已识别的风险没有判定错误；

The judgement of identified risk has not been wrong;

3.暂未发现未识别的风险。

Unrecognized residual risk was not found.

结论：风险管理小组确定无菌手术刀片及塑柄手术刀风险管理活动中无残余风险。

Conclusion: The risk management team make sure that no remaining risk in Sterile surgical blades & scalpels with plastic handle risk management activities.

4. 生产和生产后的信息 **Production and post-production information**

采集生产和生产后信息的方法，依据文件《风险管理控制程序》确定生产和生产后需要收集的信息内容，并制定《生产和生产后信息采集表》，每年度收集和更新，企业管理部管理生产和生产后的所有信息，管理者代表组织风险小组人员实施评估和汇总，采取动态风险管理，根据收集的信息进行分析和评估，必要时采取相应的纠正预防措施。

Method to collect production and post- production information. Determine the production and post-production information contents need to be collected according to Risk Management Control

Procedures, and set up the Production And Post-Production Information Collecting Form. Collect and update the information every year. System management office manage all the production and post-production information, management representatives organize risk team members to implement evaluation and summary, adopt dynamic risk management, analyze and evaluate according to the collected information. If necessary, take appropriate corrective and preventive actions.

收集相关信息和职能部门信息的途径见下面表格：

Approaches to collect related information and functional departments' information see the following form:

	生产和生产后信息 Production and post-production information	获取信息的途径/时间 Access/time to collect information	职责部门 Responsible departments
1	法规变更（如标准） Changes in regulations (such as standards)	定期在线收集 Regular online collection	体系办公室 System office
2	不良事件（内部，外部） Adverse events (internal/external)	定期在线收集：不良事件报告 Regular online collection; Adverse events reporting	质管部 Quality department
3	通知/召回 Notification / Recall	根据通知/召回程序 According to the notification/recall procedures	技术部：质量控部 Technology department; quality control department
4	监管部门监督和现场检查 Supervision and on-site inspection of regulators	定期在线收集：监督和现场检查报告 Regular online collection; Supervision and on-site inspection report	质管部 Quality department
5	客户退货信息（客户投诉/同类产品的信息） Customer return information (customer complain/Information collection of similar	调查结果（分析）：客户信息收集 Survey results (analysis); Customer information collection	销售部 Sales department

	products)		
6	设计变更 Design alteration;	设计变更审核：DFMEA, PFMEA Review on design changes; DFMEA, PFMEA	技术部 Technology department
7	采购产品的质量状态 Quality status of purchased product	使用产品部门的反馈 Feedback of the department using the product	采购部 Procurement department
8	生产过程中的问题 Problems in the process of production	纠正/预防措施 Corrective/preventative actions	生产部 Manufacturing
9	产品检测结果和留样分析 Product testing results and sample analysis	产品检测报告 Product test report	质管部 Quality department
10	产品储存的监督结果 Supervision result of product storage	监督和现场检查报告 Supervision and on-site inspection report	物流 Logistics
11	临床跟踪 PMCF Clinical follow-up PMCF	年度跟踪，纠正预防 Annual tracking, corrective and preventive action	体系办公室、临床经理 System office, clinical manager

评审小组评估《生产和生产后信息采集表》的适用性和有效性，认为这些方法是适用并有效的，可用于无菌手术刀片及塑柄手术刀生产和生产后的信息采集。

Review team evaluates the applicability and effectiveness of "production and post-production information collection form" and considered these approaches applicable and effective, and can be

used for production and post-production information collection of Sterile surgical blades & scalpels with plastic handle

我们从国外和国内市场收集上市后信息。

We collect post marketing information from abroad and domestic market.

5. 评审通过的风险管理文档 **Approved risk management file**

《安全特征问题清单及可能的危害》（见附件 1），该附件为产品设计开发之除对产品的预期用途和与安全性有关的特性以及可能危害的分析的记录。

Security Features List and Potential Hazard (see appendix 1), the appendix is the record of the intended use, security related features and analysis of potential hazard of the product at the original design and development stage.

《 风险分析和评价、控制记录》（见附件 2），该附件是对正常和故障状态下的合理可预见的危害评价、判定及控制后评价其中包括剩余风险评价的记录。

"Risk Analysis, Evaluation And Control Records" (see appendix 2), this appendix is the reasonable and foreseeable hazard evaluation, determination and evaluation after control including record of residual risk evaluation under normal and fault status.

《生产和生产后信息的收集》（附件 3），该附件产品在生产过程或临床运用中信息收集的汇总，包括同类产品的信息对比分析和评价。

"Production and Post-production Information Collection" (appendix 3), this appendix is the summary of the information collected during production or clinical use, including the comparative analysis and evaluation of similar products.

第四章　风险管理评审总结

Chapter 4　Risk Management Review Summary

在评估无菌手术刀片及塑柄手术刀后，RMRT 得出结论：

After the evaluation of Sterile surgical blades & scalpels with plastic handle, RMRT drew the conclusions:

A)风险管理计划实施适当；

The implementation of the risk management plan is appropriate;

B)单个项目的风险均有合理的降低，其收益都大于风险，均被视为是可接受；

The risk of a single project is reasonably reduced and the benefit is greater than the risks and is considered acceptable;

C)全部剩余风险处于风险可接受准则的可接受范围内，且受益超过风险；

All residual risks are within the range of the risk-acceptance criteria and the benefits are more than risks;

D)未识别到残余风险；

No remaining risk is identified;

E)生产和生产后信息采集的方法恰当。

The method of production and post-production information collection is appropriate.

无菌手术刀片及塑柄手术刀的所有剩余风险是在可接受准则的可接受范围内。

All the residual risk of Sterile surgical blades & scalpels with plastic handle is within the acceptable range of acceptable standards.

签 名：

Signature: 

日 期：2017.12.10

Date:

附录 1 安全特征问题清单及可能的危害清单

Appendix 1 Security features list and potential hazards list

安全特征问题清单及可能的危害，该清单依据 ENISO14971-2012 标准附录 C 的问题清 单和附录 E.1 危害示例，补充了有关产品的特有的安全性问题。

Security features list and potential hazard. This list added specific security features issue of related products according to the issues list and hazard examples in appendix E. 1 of ENISO14971-2012 standard appendix C.

I. 确定可能影响医疗器械安全的特征

Characteristics of affecting safety of mechanical device shall be determined.

1. 该医疗器械的预期用途是什么？如何使用该医疗器械？

What's the intended use of this medical device? How to use this medical device?

无菌手术刀片及塑柄手术刀用于切割人体的软组织。适用于外科、妇科、妇产科、泌尿科、骨科、骨科、口腔等；装配在刀柄使用。

Sterile surgical blades & scalpels with plastic handle are applied to incision soft tissues of human body in the clinic. It can be applied to surgical incision in department of surgical, gynecology, obstetrics, urology, orthopedics, orthopedics, and stomatology. Sterile surgical blade &scalpels with plastic handle are assembled on the surgical knife handles for the surgeons to cut the soft tissues.

2. 该医疗器械是预期植入的吗？

Is the medical device implanted expectedly?

不是。无菌手术刀片及塑柄手术刀用于切割人体的软组织。适用于外科、妇科、妇产科、泌尿科、骨科、骨科、口腔等。无菌手术刀片及塑柄手术刀的选用应考虑到患者切割部位。

No. Sterile surgical blades & scalpels with plastic handle are applied to incision soft tissues of human body in the clinic. It can be applied to surgical incision in department of surgical, gynecology, obstetrics, urology, orthopedics, orthopedics, and stomatology For the selection of Sterile surgical blades & scalpels with plastic handle, the patient's part of the cut shall be considered.

3. 医疗器械是否预期与患者或其他人员接触？

Is medical device expected to be in contact with patient or other persons?

无菌手术刀片及塑柄手术刀短期接触产品，可能会与临床人员短暂接触。

Sterile surgical blades & scalpels with plastic handle belongs to short-term involved contact product and it may be contact with the clinical personnel for a short time.

4.在医疗器械中利用何种材料或组分、或与医疗器械共同使用或与其接触？

Which material or component is used in the medical device? Is it jointly used with the medical device? Is it contact with the medical device?

主要材料：碳钢或不锈钢。手持刀柄进行软组织的切割。手术刀片将接触患者组织或体液，无不良反应。

Main materials: carbon steel or stainless steel. Medical personnel carry a knife handle to incision soft tissues of human body in the clinic， Sterile surgical blades & scalpels with plastic handle will be contact with patient's tissue or body fluids, no bad reaction.

5.是否有能量给予患者或从患者身上获取？

Is there energy given to patients or acquired from patients?

否。无相关事项

No. No relevant matters

6.是否有物质提供给患者或从患者身上提取？

Is there material provided to patients or acquired from patients?

否。无相关事项

No. No relevant matters

7.医疗器械是否处理生物材料用于随后的再次使用、输液/血或移植？

Is the medical device used for dealing with biological materials for the subsequent use, blood transfusion/or transplant?

否。无相关事项

No. No relevant matters

8.医疗器械是否以无菌形式提供或预期由使用者灭菌，或用其他微生物学控制方法灭菌？

Is the medical device provided in the sterile form? Is the sterilization carried out by the user expectedly? Is the sterilization carried out by other microbiological control method?

是。该产品是一次性无菌医疗器械。无菌手术刀片及塑柄手术刀产品经过辐照灭菌，辐照灭菌过程经过验证确认。

Yes.The product is disposable sterile medical device. Sterile surgical blades & scalpels with plastic handle product goes through sterilization by gamma ray, and gamma ray sterilization process is confirmed through verification.

9.医疗器械是否预期由用户进行常规清洁和消毒？

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

否。无相关事项

No. No relevant matters

10.医疗器械是否预期改善患者的环境？

Is the medical device expected to improve patient's environment?

否。无相关事项

No. No relevant matters

11.医疗器械是否进行测量？

Is the medical device measured?

否。无相关事项

No. No relevant matters

12.医疗器械是否进行分析处理？

Is the medical device analyzed?

否。无相关事项

No. No relevant matters

13.医疗器械是否预期和其他医疗器械、医药或其他医疗技术联合使用？

Is the medical device expected and jointly used together with other medical devices, medical or other medical technologies?

否。无相关事项

No. No relevant matters

14.医疗器械是否有有害能量或物质输出？

Does the medical device have harmful energy or substances output?

否。无相关事项

No. No relevant matters

15.医疗器械是否对环境影响敏感

Is medical equipment sensitive to environmental impact?

无菌手术刀片及塑柄手术刀对运输和储存环境敏感。它需要储存在干燥通风的环境中。在运输途中，需要避光、避免高温和潮湿。

Sterile surgical blades & scalpels with plastic handle is sensitive to transportation and storage environment. It needs to be stored in dry and ventilated environment. In transit, it is necessary to avoid light, high temperature and humidity.

16.医疗器械是否影响环境？

Does the medical device affect the environment?

使用后的废弃物应规范处置，避免污染环境。

After use, wastes shall be disposed regularly to avoid environmental pollution.

17.医疗器械是否有基本的消耗品或附件？

Does the medical device have basic consumables or attachments?

否。无相关事项

No. No relevant matters

18.医疗器械是否需要维护和校准？

Does the medical device need to be maintained and calibrated?

否。无相关事项

No. No relevant matters

19.医疗器械是否有软件？

Does the medical device have software?

否。无相关事项

No. No relevant matters

20.医疗器械是否有严格的储存寿命？

Does the medical device have strict storage life?

当小包装完好无损并且运输和储存正常时，有效期为 5 年。当过期使用时，可能会导致一些性能不达标造成意外。

When small-sized packing is in good condition and the transportation & storage are normal, period of validity is five years. If expired product is used, some performances cannot reach the standard to cause accident.

21.医疗器械是否有延时或长期使用效应？

Does the medical device have delayed or long-term use effects?

否。

No.

22.医疗器械承受何种机械力？

Which mechanical force is stressed on the medical device?

当手术刀片切割患者组织时，有切割力；

When the surgical blades passes through the tissue of the patient, there is cutting force;

当刀片穿过患者组织时，有阻力；

When the surgical blades passes through the tissue of the patient, there is resistance;

23.什么决定医疗器械的寿命？

What determines the service life of medical device?

产品是否按要求运输和储存。当运输和储存环境改变时（影响产品的温度和湿度），外力可能会导致小包装的密封性能以及产品性能产生变化。这些变化会影响医疗器械的寿命。

Whether the product is transported and stored according to the requirements. When the transportation and storage environment changes (temperature and humidity affecting the product), external force may cause the knot-tying of small-sized packaging, and product performance changes. These changes will affect the service life of medical device.

24.医疗器械是否预期一次性使用？

Is the medical device expected to be disposable?

是的，禁止重复使用。

Yes, it shall not be used repeatedly.

25.医疗器械是否需要安全的退出运行或处置？

Does the medical device need to be stopped or disposed safely?

在使用后无菌手术刀片及塑柄手术刀不能丢弃。它必须集中储存在一个特别容器内，并运送至医疗废物处置站。禁止重复使用。

Sterile surgical blades & scalpels with plastic handle shall not be discarded after use. Sterile surgical blades & scalpels with plastic handle must be stored in a special vessel in centralized and transported to medical waste disposal station. They shall not be used repeatedly.

26.医疗器械的安装或使用是否要求专门的培训或专门的技能？

Is special training or special skill required for installation or use of the medical device?

产品的使用必须由受过认可专业培训并获得相应资质的临床医生操作。不存在安装程序。

The use of the product must be operated by clinical doctors who are approved, trained professionally and obtain the corresponding qualifications. There is no installation program.

27.如何提供安全使用信息？

How to provide safe use information?

安全使用信息将直接通过说明书传达给终端使用者，无需培训。产品将由终端使用者处理和使用。当达到预期产品寿命时，禁止使用。

Safe use information will be directly transmitted to the end user through the instructions, without training. The product will be handled and used by the end user. When reaching the desired life, the product shall not be used.

28.是否需要建立或引入新的制造过程？

Is it necessary to establish or introduce a new manufacturing process?

否。

No.

29.医疗器械的成功使用，是否关键取决于人为因素，例如用户界面？

Is the successful use of the medical device crucially depending on human factors such as user interface?

否。

No.

30.医疗器械是否使用警报系统？

Does the medical device need an alarm system?

否。

No.

31.医疗器械可能以什么方式被故意地误用？

Which way may cause mis-operation of medical device intentionally?

无视制造商的使用提议（说明书和标识）。

Ignore use proposal of the manufacturers (instructions and identification).

32.医疗器械是否保存对患者护理非常重要的数据？

Does the medical device save data which is very important for patient care?

否。

No.

33.医疗器械是否预期用为移动式或便携式？

Is the medical device used in mobile or portable type expectedly?

否。无相关事项

No. No relevant matters

34.医疗器械的使用是否依赖于基本性能？

Does the use of medical device depend on the basic performance?

是，本产品直接用于临床，对患者进行组织等切割，取决于产品的基本性能。

Yes, the product is directly used for clinical purpose for cutting the tissue of patients, so it depends on the basic performance.

5. 危害的分析、评价和控制 **Analysis, Evaluation and Control of Hazard**

风险分析人员依据预期用途和特征判定的提示，正常和故障状态下已知和可预见的危害事件序列参考 ENISO14971.2012 附录 E.1 危害示例进行了分类，同时对可能发生的损害和初 步控制措施进行了分析/评价，记录如下表：

Risk analysis personnel refer to hazard example in Annex E.1 of ENISO14971.2012 to classify the known and foreseeable sequence of hazard events under normal and fault condition according to the intended use and prompt judged by the characteristics, and analyze/evaluate possible harm and primary control measures. Records are shown as the following table:

风险分析和评价、控制记录
Risk Analysis, Evaluation and Control Records

附录 2

4.1 危害判断分析 **The hazard judgement analysis**

危险源 **Hazard Source**	编号 **No.**	可预见的事件序列 **Predictable sequence of events**	危险处境 **Dangerous situation**	可能发生的危害 **The possibility of harm**	风险程度判定 **Judgement of risk degree**		
					损害严重度 **Damage severity**	发生概率 **probability of occurrence**	风险水平 **Risk level**
生物和化学危害 **Biological and Chemical Hazards**	H1	辐照 灭菌不彻底，或产品的使用环境不规范,操作不规范，导致产品污染 The sterilization is insufficient by Gamma ray or the use of the environment and the operation is not standardized will lead to the product's pollution	患者使用非安全性的 无菌手术刀片及塑柄手术刀 The patient used the non-safe Sterile surgical blades & scalpels with plastic handle	导致感染，可能导致永久性损伤及生命危害 Infection is caused, permanent lesion or lifethreatening hazard may be caused.	4	2	R2
	H2	组成产品的各原材料的毒性（如：碳钢或不锈钢等） The toxicity of the raw materials that make up the product (eg, carbon steel,stainless steel, inner packing material, etc.)	患者接触到还原性物质 The patient touched the reductive substance	患者机体发热，严重时导致死亡 The patient have a fever and death may be caused if it's serious.	4	2	R2
	H3	交叉或重复使用导致刀片污染 Cross use or reuse may be caused the product's pollution	患者接触重复使用的或交叉使用的刀片 The patient touched the Sterile surgical blades & scalpels with plastic handle which is cross use or reuse	可能产生感染，可能导致永久性损伤及生命危害 Infection is caused, permanent lesion or lifethreatening hazard may be caused	3	2	R2
	H4	使用包装破损或过期产品 Use the product which is damaged packaging or expired	患者使用非安全性产品 Patients use non-safety products	导致感染，严重时需要医疗手段的介入 Infection is caused and medical intervention is required if it's serious.	3	2	R2
操作危害 **Hazard of operation**	H5	操作者未经过专业技能培训 The operator has not been professionally trained	患者由未经专业技能培训的操作者实施手术 The patient is operated by an operator who has not been professionally trained	无法完成手术或导致患者产生伤害 Can not complete the operation or lead to the patient harm.	3	2	R2
	H6	非预期使用 Unexpected us	无法完成手术 Can not complete surgery,	严重导致患者死亡 Death may be caused if it's	4	1	R1

				serious.			
	H7	刀片切割过程中，刀片变形或断裂 The surgical blades body deformed or fractured in the punctured process.	患者的组织受到损伤，无法完成手术 The patient's tissue is damaged and surgery can not be complete	可能会给患者身带来伤害，严重时需要医疗手段介入。 Leading to the patient harm and medical intervention is required if it's serious.	4	3	R2
	H8	刀片锋利度不够，无法完成组织切割 Surgical blades sharpness is not enough, can not complete the organization cutting.	无法完成手术 Surgery can not be completed.	手术时间延长 prolong the operation time	2	3	R2
	H9	刀片锈迹，无法使用 Surgical blades body rust and can not be used.	患者接触非安全性产品 Patients are exposed to non-safety products	可能引起感染 Infection is caused	3	2	R2
	H10	在实施组织切割时，刀片断裂或刀片脱落。 Surgical blades broken or surgical blades fell off in the process of stitching tissue.	无法完成手术 Surgery can not be completed.	可能会给患者身体带来损伤，延长手术时间 May cause damage to the patient's body, prolong the operation time	3	3	R2
信息危害 **Hazard of information**	H11	产品上标识不明确、不清晰或不准确（如：不得重复灭菌、不得重复使用、包装破损不得使用、产品效期等）The product' s identification is unclear or inaccurate(Such as: no re-sterilization, no re-use, packaging damage shall not be used, the product' s validity, etc.)	临床操作者无法预期正确使用产品 The clinical operator can not expect the proper use of the product	导致手术失败，或患者感染，严重时需医疗手段介入 Leading to surgical failure, or patient infection, medical intervention is required if it's serious.	3	2	R2...
	H12	说明书中关于安全警告、禁忌、注意事项的说明不充分 It's not sufficient for safety warnings, contraindications and precautions in the instruction.	临床操作者无法预期正确使用产品 The clinical operator can not expect the proper use of the product	导致手术失败，或患者感染，严重时需要医疗手段介入 Leading to surgical failure, or patient infection, medical intervention is required if it's serious.	3	2	R2
	H13	对于一次性产品重复使用导致的危险警告不足 There is not enough risk warning for repeated use of disposable products	患者重复使用或交叉使用 The patient touched the suture which is cross use or reuse	导致手术失败，或患者感染，严重时需要医疗手段介入 Leading to surgical failure, or patient infection,medical intervention is required if it's serious.	3	2	R2
	H14	使用后剩余刀片应规范处置 After use, the remaining Sterile surgical blades & scalpels with plastic handle should be standardized treatment	接触人员轻微伤害 The person who contacted the suture slightly hurt	处置不当，刀片导致接触人员轻微伤害 Improper handling, the Sterile surgical blades & scalpels with plastic handle tip causes slight damage to the contact person	2	2	R1
	H15	使用后剩余刀片的处置 After use, the remaining Sterile surgical blades & scalpels with plastic handle	导致环境污染 Leading to environmental pollution	导致环境污染 Leading to environmental pollution	1	2	R1

		should be treatment					
	H16	包装标识的防护信息缺失或不准确 The protective information of the packaging logo is missing or inaccurate	患者接触非安全产品 Patients are exposed to non-safety products	患者感染，严重时需要医疗手段介入 Leading to the patient's infection, and medical intervention is required if it'sserious.	3	2	R2
环境危害 **Environmental Hazard**	H17	产品使用效期内，包装老化 The packaging was aging during product validity period	患者使用的产品带菌 The product which is used by the patient carry bacteria	患者感染，严重时需要医疗手段介入 Leading to the patient' s infection, and medical intervention is required if it's serious	3	2	R2
	H18	产品效期内性能下降（如生锈） Product performance declined during the validity period (such as rust etc)	患者使用性能有缺陷的产品 Defective products were used by the patients	无法完成手术，手术失败，或严重时导致永久性伤害 Can not complete surgery, surgery failed, or may cause permanent injury if it's serious	4	2	R2

4.2 采取措施后的危害判定分析 **Analysis to hazard judgement after taking measures**

危险源 **Hazard Source**	编号 **No**	可预见的事件序列 **Predictable sequence of events**	风险控制措施 **Risk control measures**			证明性文件 **Certification of document**	采取措施后的风险程度判定		
			固有的安全设计 **Inherent safety**	防护措施 **Protective measures**	安全信息 **Security Information**				固有的安全设计 **Inherent safety**
生物和化学危害 **Biological and Chemical Hazards** 操作危害	H1	辐照灭菌不彻底，或产品的使用环境不规范；操作不规范，导致产品污染 The sterilization is insufficient by Gamma ray or the use of the environment and the operation is not standardized will lead to the product’s pollution	1.确认产品无菌性保证水准（SAL）：10-6。产品为一次性无菌使用医疗器械， 2.产品使用前密封包装。 1. Confirm product sterility assurance level (SAL): 10-6. The product is a disposable sterile use of medical instrument 2. The product should be sealed	1.在产品出厂箱上使用灭菌指示标签。 2.辐照灭菌工艺的验证确认。 3.无菌检测作为产品出厂检验的项目之一。 1. The label which is sterile instructions should be on finished products 2.Gamma ray sterilization process validation is confirmed. 3. Aseptic testing is one of the products factory inspections.	1.标签信息“无菌”字样 2.标签和说明书明确“包装破损不得使用”字样；操作人员必须经专业技能培训。 1. The label information is "sterile" 2. Labels and instructions indicate clearly"packaging damage shall not be used"; the operators must be professional skills training	生物和化学危害 **Biological and Chemical Hazards**	H1	辐照灭菌不彻底，或产品的使用环境不规范；操作不规范，导致产品污染 The sterilization is insufficient by Gamma ray or the use of the environment and the operation is not standardized will lead to the product’s pollution	1.确认产品无菌性保证水准（SAL）：10-6。产品为一次性无菌使用医疗器械， 2.产品使用前密封包装。 1. Confirm product sterility assurance level (SAL): 10-6. The product is a disposable sterile use of medical instrument 2. The product should be sealed
	H2	组成产品的各原材料有毒性（如：碳钢或不锈钢、内层包装材料等）The toxicity of the raw materials that make up the product (eg, carbon steel, stainless steel, inner packing material, etc.)	设计开发阶段确认使用生物性能符合ISO10993要求的材料 Used the biological properties of the material should be accordance with ISO10993 in the course of design and development	1.依据ISO10993.1的要求对缝线原材料和针体原材料实施生物学检测。 2.选择合格的供方。 1. According to the requirements of ISO10993.1 suture and needle body’s raw materials carry out biological testing. Select a qualified supplier.	生物学评价报告 biological evaluation report		H2	组成产品的各原材料有毒性（如：碳钢或不锈钢、内层包装材料等）The toxicity of the raw materials that make up the product (eg, carbon steel, stainless steel, inner packing material, etc.)	设计开发阶段确认使用生物性能符合ISO10993要求的材料 Used the biological properties of the material should be accordance with ISO10993 in the course of design and development
	H3	交叉或重复使用导致刀片污染 Cross use or reuse may be caused the product’s pollution	说明书、标签的设计 Design of the instruction and label	标签和说明书提出警示。Warning in the labels and instructions	标签和说明书明确“不可重复使用”图示和文字说明，说明书明确重复和交叉使用的不良后果警示 Labels and instructions put forward clearly by markand description"non-reusable" ,make the warning about adverse consequence of re-use and cross use in the instructions		H3	交叉或重复使用导致刀片污染 Cross use or reuse may be caused the product’s pollution	说明书、标签的设计 Design of the instruction and label

	H4	使用包装破损或过期产品 Use the product which is damaged packaging or expired	说明书、标签的设计 Design of the instruction and label	标签和说明书提出警示。 Warning in the labels and instructions	标签和说明书明确“包装破损不得使用”图示和文字说明，产品包装清晰显示产品效期。 Labels and instructions put forward clearly by mark and description"packaging damage shall not be used" .product packaging clearly shows the product validity.		H4	使用包装破损或过期产品 Use the product which is damaged packaging or expired	说明书、标签的设计 Design of the instruction and label
	H5	操作者未经过专业技能培训 The operator has not been professionally trained	说明书的设计 Design of the instruction	说明书提出警示。 Warning in the instructions	说明书明确产品的使用者必须是“经过专业技能培训“剩余缝线应规范处置”的文字描述 Labels and instructions put forward clearly by mark and description"after the professional skills training" "the remaining suture should be standardized disposal	操作危害	H5	操作者未经过专业技能培训 The operator has not been professionally trained	说明书的设计 Design of the instruction
信息危害	H6	非预期使用 Unexpected use	说明书设计 Design of the instruction	说明书明确产品的预期用途 The specification clarifies the intended use of the product	说明书文字描述产品的预期用途：于软组织缝合和（或）结扎，不用于心血管组织和神经组织” Describe the intended useof the product "for soft tissue suture and / or ligation, not for cardiovascular tissue and nerve tissue"		H6	非预期使用 Unexpected use	说明书设计 Design of the instruction
	H7	刀片在切割过程中，刀片变形或断裂 Thesurgical blades body deformed or fractured in the cutting process.	选用合格牌号的医用碳钢或不锈钢 Select qualified grades of carbon steel or stainless steel	1.材料检测 2.产品制造过程中，刀片热处理的参数确认 3.成品的性能检测 4.选用适用规格的刀片 5.使用人员的规范操作，避免手术等器械损伤刀片。 1. Materia inspection 2. In the process of product manufacturing, the parameters of surbical blades heat treatment are confirmed. 3. Performance testing of finished product 4. Use the appropriate size of the surgical blades andthread, 5.Regulate the operation by	说明书中明确： 1.根据临床的需要选择合适规格的刀片 2.产品的使用人员“经过专业技能培训” Indicate in the instructions: 1. the choice of the surgical blades should be in line with the clinical needs 2. Product users should be through professional skills training		H7	刀片在切割过程中，刀片变形或断裂 Thesurgical blades body deformed or fractured in the cutting process.	选用合格牌号的医用碳钢或不锈钢 Select qualified grades of carbon steel or stainless steel

				the user, to avoid the damage of the surgical blades body clamp,surgical scissors and other equipment damage					
	H8	在实施组织切割时， 刀片断裂或脱落。Thesurgical blades broken or Surgical blades fell off when cutting the tissue	选用合格的刀片。 Select the surgical blades which is qualified of the specification	1.刀片的弹性、韧性，刀片与刀柄的连接强度检测 The flexibility, toughness, blade and handle connection strength of the blade are tested	说明书中明确： 1.根据临床的需要选择合适规格的刀片 2.产品的使用人“过专业技能培训” Indicate in the instructions:1. According to the clinical application, select the appropriate specifications of the surgical blades 2. The user of the product should be through professional skills training"		H8	在实施组织切割时， 刀片断裂或脱落。Thesurgical blades broken or Surgical blades fell off when cutting the tissue	选用合格的刀片。 Select the surgical blades which is qualified of the specification
	H9	刀片锋利度不够，无法完成组织切割 Surgical blades sharpness is not enough, can not complete the organization cutting.	产品技术要求 Product technical requirements	规范刀片锋利度的过程检测，成品最终检测。 Standard the process testing Ofsurgical blades’s sharpness and the final product testing.	产品技术要求中确定锋利度参数 Technical requirements to determine the sharpness parameters		H9	刀片锋利度不够，无法完成组织切割 Surgical blades sharpness is not enough, can not complete the organization cutting.	产品技术要求 Product technical requirements
	H10	刀片锈迹，无法使用 Surgical blades body rust and can not be used.	选择合格的牌号碳钢或不锈钢 Choose the carbon steel or stainless steel which is qualified trade mark	供方资质的确认储存、运输环境确认 Confirmation of supplier qualification,storage and transportation environment	说明书中警示：刀片有锈迹，禁止使用 Instruction warnings: Not use if the surgical baldes body rust		H10	刀片锈迹，无法使用 Surgical blades body rust and can not be used.	选择合格的牌号碳钢或不锈钢 Choose the carbon steel or stainless steel which is qualified trade mark
	H11	产品标识不明确，不清晰或不准确：（如：不得重复灭菌，不得重复使用，包装破损不得使用，产品效期等） The product’s identification is unclear or inaccurate (Such as: no re-sterilization, no re-use, packaging damage shall not be used, the product’s validity, etc.)	依据ISO15223.1确定产品标识。 Determine the product identification according to ISO 15223.1.	产品包装标签图示、文字、符号，效期等信息的检测和确认 Mark,wordage, symbols and validity of the product detection and confirmation	说明书和标签信息的内容的符合性的确认 The confirmation of the contents of the instructions and labels	信息危害	H11	产品标识不明确，不清晰或不准确：（如：不得重复灭菌，不得重复使用，包装破损不得使用，产品效期等） The product’s identification is unclear or inaccurate (Such as: no re-sterilization, no re-use, packaging damage shall not be used, the product’s validity, etc.)	依据ISO15223.1确定产品标识。 Determine the product identification according to ISO 15223.1.

	H12	说明书关于安全警 告、禁忌、注意事项 说明不充分 It’s not sufficient for safety warnings, contraindications and precautions in the instruction.	说明书、标签设计 Design of the instruction and label	确认说明书中明确产品的 禁忌、警告和注意事项的描 述是否充分 Confirm the description of the product's contraindication, warning and cautions is sufficient	说明书充分显示中关于安 全警告、禁忌、注意事项 文字描述。 The instructions are fully displayed on the safety warning, contraindication and cautions		H12	说明书关于安全警 告、禁忌、注意事项 说明不充分 It’s not sufficient for safety warnings, contraindications and precautions in the instruction.	说明书、标签设计 Design of the instruction and label
环境危害	H13	对于一次性产品重 复使用导致的危险 警告不足 There is not enough risk warning for re-use of disposable products	说明书、标签设计 Design of the instruction and label	标签说明书中图形和文字 的表示 The representation of mark and wordage in the instruction	1.产品标签明确“不得重 复使用”的符号 2.说明书中明确重复使用将导致：刀片断裂、污染、刀片与刀柄脱落等，术后可导致发热、感染等！ 1. Indicate in the label of the product:"Do not re-use" 2. Indicate in the instructions: surgical blades break, dirt, connection of surgical blades and plastic handle break and for the patient more risks after surgery, can lead to fever, infection and so on		H13	对于一次性产品重 复使用导致的危险 警告不足 There is not enough risk warning for re-use of disposable products	说明书、标签设计 Design of the instruction and label
	H14	包装标识的防护信 息缺失或不准确 The protective information of the packaging logo is missing or inaccurate	确认产品的储存、运输防护环境要求 Confirm the storage of the product, transport protection and environment requirements	1.产品标识和说明书明确 储存运输的标识和文字描 述。 2.包装运输验证确认 1. Indicate in the label and instruction:the transport logo and wordage description. 2.Packing and transport verification	产品的外包装和中盒包装 标识明确“避免阳光直 射”、“保持干燥”、“易碎， 小心操作”符号警示 Indicate in the mark of the product and medium box packaging "to avoid direct sunlight", "keep dry", "Fragile, Handle with care"		H14	包装标识的防护信 息缺失或不准确 The protective information of the packaging logo is missing or inaccurate	确认产品的储存、运输防护环境要求 Confirm the storage of the product, transport protection and environment requirements
	H15	使用后剩余刀片应 规范处置 After use, the remaining surgical blades should be standardized treatment	说明书设计 Design of the instruction	产品说明书明确剩余刀片 规范处理要求 The product specification specifies standardize disposal requirements of the remaining surgical blades	说明书中对剩余刀片处置 描述：使用后的剩余刀片 应规范处置，防止刀片尖对 接触人员产生伤害 Indicate in the instruction : After use, the remaining Surgical blades should be standardized		H15	使用后剩余刀片应 规范处置 After use, the remaining surgical blades should be standardized treatment	说明书设计 Design of the instruction

					treatment to prevent the tip of the contact personnel to harm				
	H16	使用后剩余刀片使 用后处置 After use, the remaining surgical blades should be treatment	说明书设计 Design of the instruction	产品说明书明确剩余刀片 规范处理要求 The product specifies standardize disposal requirements of the remaining surgical blades	说明书中对剩余刀片处置 描述：使用后的剩余刀片 应规范处置，避免环境污 染 Indicate in the instruction:After use,the remaining surgical blades should be standardized disposal, to avoid environmental pollution		H16	使用后剩余刀片使 用后处置 After use, the remaining surgical blades should be treatment	说明书设计 Design of the instruction
	H17	产品使用效期内，包 装老化 The packaging was aging during product validity period	确认产品的储存、运输防护环境要求 Confirm the storage of the product, transport protection and environment requirements	1.包装运输验证 2.产品的 3 年效期老化验证（分别验证 3 年和 5 年的效期老化试验） 1. Packing and transport verification 2. 3-year aging of the product (Validation of 3-year and 5-year aging tests, respectively)	1.标签和说明书明确“包 装破损不得使用”警示. 2.说明书明确产品的储存 条件：建议储存在湿度小 于 80%的清洁通风环境； 避免阳光直射或热源。 1. Indicate in the label and instruction "packaging damage shall not be used" 2.Indicate in the instruction: stored in a clean and ventilated environment with a humidity of less than 80%, avoid to direct sunlight or heat source.	环境危害	H17	产品使用效期内，包 装老化 The packaging was aging during product validity period	确认产品的储存、运输防护环境要求 Confirm the storage of the product, transport protection and environment requirements
	H18	产品效期内性能下 降（如生锈） Product performance declined during the validity period (such as rust)	确认材料符合性 储存、运输防护环境的确认 Confirm the storage of the product, transport protection and environment requirements	1.进料检验 2.包装运输验证 3.产品的储存环境的确认 1. Incoming quality inspection 2. Packing and transport verification 3.Confirmation of the product’s storage environment	说明书明确产品的储存条 件：建议储存在湿度小于 80%的清洁通风环境；避 免阳光直射或热源 Indicate in the instruction: stored in a clean and ventilated environment with a humidity of less than 80%; avoid to direct sunlight or heat source		H18	产品效期内性能下 降（如生锈） Product performance declined during the validity period (such as rust)	确认材料符合性 储存、运输防护环境的确认 Confirm the storage of the product, transport protection and environment requirements

附录 3 生产和生产后信息

Appendix 3 Production and post-production information

1. 2010-2014 年生产和生产后信息的收集汇总如下：

Collection and summary of 2010-2014 production and post-production information are as follows:

FDA 网站上的获取的数据

Data acquired from FDA website

(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?ID=2271&min_report_year=2007) 目前为止，主要的器械问题如下：

So far, major equipment problems are as follows:

不符合项 **Non-Compliance**	频次**Frequency**	预防措施**Precautions**	有效性检查 **Validity check**
破裂break	440 次 440times	最终产品检查 Final product inspection	已完成-是 Completed - Yes
其他（用于无法识别相应的器械代码时使用） Others (use when failing to identify corresponding instruments code)	402 次 402 times	最终产品检查 Final product inspection	已完成-是 Completed - Yes
反应 Responding	97 次 97 times	最终产品检查 Final product inspection	已完成-是 Completed - Yes
部件破裂 Components break	3 次 3 Nos.	最终产品检查 Final product inspection	已完成-是 Completed - Yes
刀尖断裂 Tool nose fracture	4 次 4 times	在标签中附上警告以提示使用者 Attach a warning on label to prompt the user	已完成-是 Completed - Yes
器械使用的问题 Problems in using the instrument	11 次 11 times	在标签中附上警告以提示使用者 Attach a warning on label to prompt the user	已完成-是 Completed - Yes

以下信息是关于 无菌手术刀片及塑柄手术刀产品的召回事件：

The following information is about Sterile surgical blades & scalpels with plastic handle product recalls:

召回 Recall					
Year		2010	2011	2012	2013
1	Type1	0	0	0	0
2	Type2	2	1	1	1
3	Type3	0	0	0	0

召回 Recall			
制造商 Manufacturer		召回类型 Recall type	发布日期Date of issue
1	C P Medical Inc	2 类 Type 2	2011 年11 月19 日 2011.11.19
2	Coloplast Manufacturing US, LLC	2 类Type 2	2013 年6 月5 日 2013.06.05
3	Ethicon. Inc.	2 类Type 2	2010 年5 月18 日 2010.05.18
4	Mani.Inc.-Kiyohara Facility	Type 2	2012 年1 月11 日 2012.01.11
5	Telefelx Medical	2 类 Type 2	2010 年 8 月 26 日 2010.08.26

在当地，我们还收到了一些来自消费者对于该产品的投诉，不正确的标注导致的，组件错误搭配。

We have also received some complaints from local consumers for the product. The main problems are components due to incorrect labeling.

我对此处不一致的原因进行了分析，做出了相关的矫正解决这些问题。同时在无菌手术刀片及塑柄手术刀产品质量控制的过程中，我们采取了一些预防措施以纠正 FDA 网站上所列的可能不符合项，从而确保我们产品的安全性和有效性。

I analyzed the reasons of inconformity and took measures to solve these problems. Meanwhile during the quality control of Sterile surgical blades & scalpels with plastic handle, we have taken some preventive measures to correct the Nonconformance on FDA website, thus ensuring the safety and effectiveness of our product.

自我公司产品销售以来，直到现在，我们接到过两次客户对于产品损坏和刀尖破裂的投诉，我们也同样进行了有效的矫正工作。

Since the selling of our products, we have received two customer complaints for product damage and broken tool nose, we also conducted effective corrective work.

II. 2015 年 8 月至 2016 年 8 月，对生产和生产后信息的收集如下：

From August 2015 to August 2016, the information collected during production and after production is as follows:

1.法规（标准）变更 **Changes in regulations (standards):**

序号 S/N	现行法规/标准 Current regulations/standards	代替标准 GB	发布日期 Date of Issue	生效日期 Effective Date	评估意见 Evaluation Opinion
1	ISO13485-2016	ISO13485-2003			适用 Applicable

2.不良事件 **Adverse events:**

2.1 中国境内 CFDA 网站：

根据国家食品药品监督管理总局 http://nmpa.gov.cn 网站上获取的数据显示：2015 年 1 月 1 日至今，暂无无菌手术刀片及塑柄手术刀的不良事件报告。

Food and Drug Administration in China:

According to the CFDA website (http://nmpa.gov.cn) show that there's no adverse event report of Sterile surgical blades & scalpels with plastic handle since January 1, 2015 to now.

2.2 根据 **FDA** 网站

http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm352320.htm

获取的信息显示：

Food and Drug Administration in US:

According to the FDA website

http://accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=5646&min_report_year=2016

show that there is only one adverse event report, and specific information is as follows:

TPLC - Total Product Life Cycle

FDA Home | Medical Devices | Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards | CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | show TPLC since: 2016 | Back to Search Results

Device	Blade, Saw, Surgical, Cardiovascular
Regulation Description	Surgical instrument motors and accessories/attachments.
Product Code	DWH
Regulation Number	878.4820
Device Class	1

MDR Year	MDR Reports	MDR Events
2016	1	1
2017	3	3
2018	1	1
2019	1	1
2020	2	2

Device Problems	MDRs with this Device Problem	Events in those MDRs
Break	6	6
Fracture	3	3

Patient Problems	MDRs with this Patient Problem	Events in those MDRs
No Consequences Or Impact To Patient	5	5
No Patient Involvement	3	3

译文：

无菌手术刀片断裂。

2016 年至今

分析：警告信中提及的手术刀片断裂现象，可能导致产品临床非预期使用，目前，我公司尚未发生类似的不合格，但是这种不合格，给我们在产品制造过程中，提出了警惕。消除潜在风险的措施：规范执行清场 SOP 加强产品检验和过程控制。

Analysis: The warning letter mentioned break of surgical blades that could cause the product not use in clinical. At present, our company has not been a similar unqualified , but this failed to give us alert in the manufacturing process .Measures to eliminate potential unqualified: To implement clearance SOP normatively.To enforce the inspection of the product and manufacture control.

2.3 UK 网站的信息 https://www.gov.uk/drug-device-alerts?keywords=surgical+blade&alert_type%5B%5D=devices&issued_date%5Bfrom%5D=&issued_date%5Bto%5D=

2016 年 1 月 1 日至今，暂无无菌手术刀片及塑柄手术刀不良事件报告。

Medicines & Health care products Regulatory Agency in UK:

According to the website

https://www.gov.uk/drug-device-alerts?keywords=surgical+blade&alert_type%5B%5D=devices&issued_date%5Bfrom%5D=&issued_date%5Bto%5D=

show that there's no adverse event report about Sterile surgical blades & scalpels with plastic handle

注：15 例不良事件都与手术刀片及塑柄手术刀无关。

Note: 15 deverse events all have nothting to do with Sterile surgical blades & scalpels with plastic handle

2.4 根据 (澳大利亚 **FDA) https://www.tga.gov.au/medical-devices-safety**

网站上获取的数据显示：2016 年 1 月 1 日至今，暂无无菌手术刀片及塑柄手术刀不良事件报告。Therapeutic Goods Administration (TGA) /Australian Government Department of Health: According to the website (https://www.tga.gov.au/medical-devices-safety) show that there's no adverse event report about Sterile surgical blades & scalpels with plastic handle from January 1st,2016 to now.

分析：根据在上述各网站的收集，目前上尚未发现我公司生产的无菌手术刀片及塑柄手术刀的不良事件报告。同类产品的不良事件（警告信息），目前只有一例，对我们产品来讲是一种警惕，我们已采取了相应的纠正预防。我们会持续收集网站发布的信息。

Based on the information from these websites, to sum up, we haven't found the adverse event report which was about our company produced Sterile surgical blades & scalpels with plastic handle. There was only one case about adverse event of the similar product, It was an alert for our products, we have taken the corresponding corrective and preventive measures, and we will continue to focus on the website information

3.通知/召回 **Notification / recall**

3.1 根据 CFDA 网站：http://www.sda.gov.cn/WS01/CL0001/网站上获取的数据显示：2015 年 1

月 1 日至今，中国境内暂无无菌手术刀片及塑柄手术刀召回事件报告。

Food and Drug Administration in China:

According to the CFDA website (http://www.sda.gov.cn/WS01/CL0001/) show that there's no recall report of Sterile surgical blades & scalpels with plastic handle from January 1st, 2015 to now.

3.2 根据 **FDA** 网站 Food and Drug Administration in US:

信息显示：According to the FDA website

http://accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm

有一例刀片装在刀柄上松动产生的产品召回。

3.3.UK 网站信息 **Medicines & Health care products Regulatory Agency in UK**:

http://www.gov.uk/drug-device-alerts?keywords=+blades&alert_type%5B%5D=device-safety-information&issued_date%5Bfrom%5D=1%2F1%2F2019&issued_date%5Bto%5D=1%2F1%2F2021

网站上获取的数据显示：

2019 年 1 月 1 日至今，暂无无菌手术刀片及塑柄手术刀召回事件报告。

According to the websitehttp://www.gov.uk/drug-device-alerts?keywords=+blades&alert_type%5B%5D=device-safety-information&issued_date%5Bfrom%5D=1%2F1%2F2019&issued_date%5Bto%5D=1%2F1%2F2021 show that there's no recall report about Sterile surgical blades & scalpels with plastic handle from January 1st2019 to 2021, and the specific information is as follows:

3.4 根据澳大利亚 FDA 网站 https://www.tga.gov.au/medical-devices-safety

网站上获取的数据显示：2016 年 1 月 1 日至今，暂无无菌手术刀片及塑柄手术刀召回事件报告。

Therapeutic Goods Administration (TGA) /Australian Government Department of Health:According to the website (https://www.tga.gov.au/medical-devices-safety)show that there's no recall report about Sterile surgical blades & scalpels with plastic handle from January 1st, 2016 to now.

4.监管部门监督和现场检查 **Regulators supervise and spot-check:**

4.1 地方主管机构的日常监管 Local authority's daily supervision

4.1.1 2017 年 10 月 24 日-25 日, JS FDA 对我公司进行为期 2 天日常监督检查。

检查结果：无菌医疗器械不符合项共 11 项；其中关键项 0 项，一般项 11 项。

不符合项主要体现在过程记录填写不规范、工作服穿戴不规范、销售台账不够明细等，我公司针对不符合项已完成整改，并对进行跟踪验证，结果显示整改有效。

October 24th to 25th,2017, JSFDA (JiangSu Province Food and Drug Administration) came to our company for two days the routine supervision and inspection.

Findings:There were 11 nonconforming items for sterile medical devices, included 0 key item and 9 general items. Nonconformity was mainly reflected in the process of recording fill in irregularity, non-standard work clothes worn, sales ledger was not enough detail, etc.

The nonconformity has been completed rectification, and track verification resulted show that it was corrective and effective.

4.1.2. 2020 年 4 月 2 日 JS FDA 对我公司进行为期 1 天日常监督检查。
检查结果：无菌医疗器械不符合项共 7 项；其中关键项 0 项，一般项 7 项。不符合项主要体现在过程记录填写不规范、工作服穿戴不规范、销售台账不够明细等，我公司针对不符合项已完成整改，并对进行跟踪验证，结果显示整改有效。

April 2th ,2017, JSFDA (JiangSu Province Food and Drug Administration) came to our company for two days the routine supervision and inspection.

Findings:There were 11 nonconforming items for sterile medical devices, included 0 key item and 9 general items. Nonconformity was mainly reflected in the process of recording fill in irregularity, non-standard work clothes worn, sales ledger was not enough detail, etc.

The nonconformity has been completed rectification, and track verification resulted show that it was corrective and effective.

5.客户退货信息（客户投诉） **Information of customers return the goods (customer complaint)**

2015 年 1 月 1 日起至今，我公司未收到客户要求退货的信息。客户投诉的报告，详情如下：

So far, our company has not received information from the customer demands the return from January 1st, 2015. The customer complaint report as follows:

6. 设计变更 **Design changes**
我公司生产的无菌手术刀片及塑柄手术刀产品上市销售以来，没有设计变更。

Since my company's Sterile surgical blades & scalpels with plastic handle on sale, there 's no design changes

7. 采购产品的质量状态（使用产品部门的反馈）
Quality status of the purchasing products.

7.1 严格执行公司的采购控制程序。

Implement company's procurement control procedures strictly .

7.2 采购产品的质量状态稳定，有固定的合格供应商，2019 年 1 月 1 日-至今，没有使用部门和检测部门反馈无菌手术刀片及塑柄手术刀主要原材料的使用不合格的信息。

The purchasing product's quality is stable, and we have a fixed qualified suppliers. There's no feedback about using the main raw material unqualified information from using department and inspection department since January 1st,2019 to now.

8.生产过程中的问题（纠正/预防措施） **Problems during the manufacturing process.**

2016 至 2017 年 10 月，生产过程中没有出现严重不合格现象,风险在可控范围，生产过程中的现场管理存在一些不规范现象：

The production process had not serious unqualified phenomenon from January 1st,2016 to now,. The risk is under control, but there are some nonstandard phenomena in the process of production on-site management.

8.1 设备维护、保养记录填写不规范（例如：签名、日期）

Equipment maintenance and maintenance records to fill was non-standard (for example: signature, date)

8.2 回风口堆放物料

Return air stacked material.

相应的纠正/预防措施 Corrective / preventive measures:

设备管理人员严格按照设备维护保养 SOP 执行，及时、完整的记录设备运行维护情况

Equipment management personnel need to implement strictly equipment maintenance SOP, timely and complete recording equipment operation and maintenance situation.

移除和清理回风口处物料，保持风流畅通。

Remove and clean up the materials at the return air to maintain smooth airflow.

9. 产品检测结果和留样分析 **Products test result and analysis for the kept samples.**

9.1 2016 至 2017 年，在客户的抽样和主管机构的监督抽样检测中，全部合格，对产品的过程检验和成品检测，未出现影响产品主要性能的不合格。

From 2016 to 2017, in the customer's sample and supervisory organ's sampling inspection, our products were all qualified.

9.2 严格执行产品的留样 SOP,对 无菌手术刀片及塑柄手术刀 产品在 5 年效期内稳定性试验跟踪检测，记录并评估检测数据，2016 年 1 月 1 日至 2017 年，跟踪数据显示，产品效期内安全有效，所有性能符合技术要求。

Strictly implement SOP about the retention samples of the products, and test on the stability of Sterile surgical blades & scalpels with plastic handle within five years lifetime, record and evaluate testing data. From January 1st,2016 to 2017, the tracking data indicated that the product was safe and effective within the lifetime, and all properties meet technical requirements.

10. 产品储存的监督结果 **Supervised results for the products storage.**

产品的储存严格执行产品的环境储存要求，适时的监测产品的储存环境并记录归档。2019 年至今，产品的储存环境受控。没有发生因产品的储存环境而引起的不合格。

The storage of the product strictly enforce environmental storage requirements, timely monitoring product storage environment and documenting. The storage environment was under control. There's no substandard product due to storage conditions.

结论 **Conclusion:**

综上所述，生产和生产后信息的收集符合《风险管理控制程序》的要求，风险的管理小组能够按照确定的《生产和生产后信息采集表》进行，尽管我们所获得的数据可能存在遗漏或不足，我们会持续不间断的收集，识别不合格和潜在不合格，并实施纠正预防。对产品的风险实施动态管理。

In summary, production and post-production of collecting information in line with the requirement of risk management and control procedures. The risk management team base on the production and post-production information collection form. In spite of the data we have obtained may miss or less, we will continue to uninterrupted collect, at the same time, identify nonconformity and potential nonconformity, and then implement corrective and preventive measures.