文件编号 DN：QP200	版本号 Version：
主管部门 Resp. Dept.：质量部	发放编号 Distribution No.:

XXXXXXX 有限公司

质量管理体系程序文件

QUALITY SYSTEM PROCEDURE

不合格品控制程序
Nonconformity Control Procedure

编制 Initiated by：___

审核 Reviewed by：___

批准 Approved by：___

发放范围(applied for)：各部门 Various departments　　生效日期(Effective Date)：2017 年 02 月 09 日

目　　录

序号　内容　页码

1. 目的 Purpose

本程序规定对不合格品从识别、隔离到评审处置进行有效控制，以防止非预期的使用。对不符合要求的行为造成的后果进行调查，正确评估影响，以做出相应的处置。

This procedure specifies requirements for effectively controlling nonconforming products of identification, separation, review and handling to prevent the unintended use. It also regulates that consequences resulting from nonconforming activities shall be investigated, accurately evaluated and correspondingly disposed.

2. 适用范围 Scope

本程序适用于从采购产品进厂到成品出厂的所有阶段的不合格品的控制以及退回不合格品的处置。

This procedure is applicable to controlling nonconforming products of all phases from the products purchased to the factory to their delivery, as well as handling of returned nonconforming products.

3. 职责 Responsibilities

3.1 质量部:

Quality Department:

a. 对原辅料、半成品和成品检验项目的符合性进行评估，收集整理相关数据，描述不合格状况并传递相关信息至各功能单位进行处理；对不合格品进行标识;

Evaluate the conformity of inspection items for raw material, ancillary materials, semi-finished products and finished products, collect and summarize relevant data, describe nonconforming conditions and pass relevant information to each functional division to handle the nonconformities, and identify the nonconforming products.

b. 负责组织对不合格产生的原因进行调查，确定对不合格品的处理措施。

Organize interested divisions to investigate the cause of the nonconformities and determine the handling measures to the nonconforming products.

3.2 生产部:

Manufacturing Department:

a. 负责对生产过程中发现的不合格品进行标识、隔离和报告；

Identify, separate and report the nonconforming products found during the manufacturing process.

b. 协助质量部对不合格品进行原因调查、风险分析、并采取纠正/预防措施。

Give assistance to the quality department to investigate the cause of the nonconforming products and to analyze related risks, and take corresponding corrective or preventive actions.

3.3 生产技术部:

Manufacturing Techniques:

a. 协助质量部对不合格品进行原因调查、风险分析、并采取纠正/预防措施;

Give assistance to the quality department to investigate the cause of the nonconforming products and to analyze related risks, and take corresponding corrective or preventive actions.

b. 对不合格品的处置、评审提供技术支持。

Provide technical supports to handle and review the nonconforming products.

3.4 采购部负责联络供应商，反馈不合格原辅料信息及协助不合格原辅料的处理;

Purchasing Department shall take charge of contacting suppliers, feeding back information about nonconformities of raw materials and ancillary materials, and give assistance to handle such nonconformities.

3.5 仓库负责对产品、原辅料在入库、储存、出库等过程中发现的不合格品进行隔离和报告;

Warehouse shall take charge of separating and reporting the nonconforming products found during the processes when products, raw materials and ancillary materials are warehoused, stored, delivered, etc.

3.6 研发部负责对转用于研究使用的不合格品进行控制，防止与正常品混用;

R&D shall take charge of controlling the nonconforming products for research uses to prevent from being mixed with authentic products.

4. 不合格原辅料的控制 Control of Nonconforming Raw Materials

4.1 原物料不合格的报告

Report of nonconforming raw materials

4.1.1 进货检验中发现不合格原辅料，由质量部 QC 将检验结果记录在相应原辅料来料检验报告单上，不合格信息发至物流管理部，并填写 QP200-RE-01《不合格品处理报告单》，提交给 QA 进行处理。

Nonconforming raw materials found in the incoming inspection shall be recorded in the *Incoming Inspection Report* by QC of the Quality Department. The conforming information shall be sent to the Logistics management. And the Nonconformity Handling Report (QP200-RE-01) shall be completed and submitted to QA to handle the nonconforming products.

4.1.2 生产部在生产过程中发现的不合格原辅料，应作好隔离，当数量、比例或严重程度超出标准范围时，按 QR204《生产异常处理操作程序》执行，同时尽量提供不合格样品或图片。

Nonconforming raw materials found in the manufacturing process shall be separated by the Manufacturing Department. Conditions shall be conducted according to the *Manufacturing Deviation Handling & Operating Procedure* (QR123) when quantity, proportion or severity is out of the ranges. Meanwhile, the nonconforming

samples or photos shall be provided.

4.1.3 质量部 QC 对不合格品做好标识；仓库/生产对不合格品移入不合格区进行隔离。

QC of the Quality Department shall identify the nonconforming products, while Warehouse or Manufacturing Department shall physically separate the nonconforming products to the rejected areas.

4.2 原物料不合格的原因调查

Investigation of raw material nonconformities

4.2.1 质量部 QA 接到 QP200-RE-01《不合格品处理报告单》后，组织对不合格原因进行调查，依据附表 1《风险评估表》进行风险评估，若涉及功能性问题由生产技术调查并进行风险评估。

QA of the Quality Department shall organize interested divisions to investigate the cause of the nonconformity after obtaining the *Nonconformity Handling Report* (QP200-RE-01) and evaluate related risks according to the *Appendix 1 Risk Evaluation Form*. If any performance issues are concerned, the Manufacturing Techniques shall investigate the nonconformity and perform the risk evaluation.

4.2.2 因供应商问题造成的原物料不合格，由质量部根据风险评估结果决定是否需给供应商发出 QP110-RE-04《供方质量信息反馈单》(风险评估结果为高的，必须启动《供方质量信息反馈单》；风险评估结果为低或中的，依据不合格的具体情况进行确定)；并将相应的 QP110-RE-04《供方质量信息反馈单》单号记录在 QP200-RE-01《不合格品处理报告单》中。

According to the result of risk evaluation, the Quality Department shall determine whether a *Supplier's Quality Information Feedback* (QP110-RE-04) is required to send to the supplier if the raw material nonconformities result from suppliers. (A *Supplier's Quality Information Feedback* must be initiated if the result of risk evaluation is high. For a medium or low risk evaluation result, whether a *Supplier's Quality Information Feedback* is necessary or not shall be determined according to the specific conditions of the nonconformity.) And the corresponding number of the *Supplier's Quality Information Feedback* (QP110-RE-04) shall be recorded in the *Nonconformity Handling Report* (QP200-RE-01).

4.2.3 因本公司原因造成的原物料不合格，质量部根据风险评估结果评估是否需要启动 CAPA（风险评估结果为高的，必须启动 CAPA；风险评估结果为低或中的，依据不合格的具体情况确定是否启动 CAPA），并将 CAPA 单号记录在相应的报告单中。CAPA 的操作依据 QP220《纠正和预防措施控制程序》进行。

For raw material nonconformities resulting from our company, the Quality Department shall determine whether a CAPA is necessary to initiate or not according to the result of risk evaluation (A CAPA must be initiated if the result of risk evaluation is high. For a low or medium risk evaluation result, whether a CAPA is necessary to open or not shall be determined according to the specific conditions of the nonconformity). And the number of the CAPA shall be recorded in the corresponding report. The operation of CAPA shall refer to the *Corrective and*

Preventive Action Control Procedure (QP220).

4.3 原物料不合格的处置

Handling of raw material nonconformities

4.3.1 拒收：因供应商原因造成的不合格退回供应商，将结果记录在 QP200-RE-01《不合格品处理报告单》中。

Rejection: nonconformities resulting from suppliers shall be returned to the specific supplier and the result shall be recorded in the *Nonconformity Handling Report* (QP200-RE-01).

4.3.2 报废：因本公司原因造成的不合格作报废处理。

Scrap: nonconformities resulting from our company shall be scrapped.

4.3.3 让步接收：由于特殊情况，原物料不影响产品的使用功能、性能，符合法律法规，自相应原辅料来料检验报告单发出之日算起至下个工作日止（节假日除外），物料需求部门可提出让步接收申请，填写 QP200-RE-02《让步接收申请单》，并根据质量部要求组织评审并进行风险分析（依据附表 1《风险评估表》进行），最终由质量部决定是否可以让步接收，若质量部无法形成最终结论的，由总经理决定，并将最终处理为让步放行的 QP200-RE-02《让步接收申请单》单号记录在《不合格品处理报告单》中。（物料需求部门为视物料不合格情况确定）

Concession: due to special conditions, for raw materials not affecting the product function and performance and conforming to laws and regulations, the material-demanded department can apply for a concession with a completed *Concession Application Form* (QP200-RE-02) from the day when the *Incoming Inspection Report* is issued to the next workday (excluding holidays). Also, based on the requirement of the Quality Department, interested divisions shall be organized to review the application and perform the relevant risk evaluation (according to the *Appendix 1 Risk Evaluation Form*). Finally, the Quality Department shall determine whether the concession is accepted or not. If the Quality Department can't give a final conclusion of the concession, the general manager shall determine whether the concession is accepted or not 。 If the concession is accepted, the number of the *Concession Application Form* (QP200-RE-02) shall be recorded in the corresponding *Nonconformity Handling Form*. (The material-demanded department shall be confirmed according to the nonconformities of the materials.)

4.3.4 其它：如上述处理方式均不适用，应将处理方式描述清楚。例如启动产品更改、人员培训以及文件修订等。其中涉及产品更改，根据 QR086《更改评估程序》和 QP090《更改控制程序》执行；人员培训根据 QR031《培训管理程序》执行；文件修订根据 QP000《文件控制程序》执行。

Others: if above handling methods are all not applicable, the handling methods shall be clearly described.

For example, start the product change, training and document revision etc. About the product change, shall be conducted according to the *Change Control Procedure* (QP090) and *Change Assessment Procedure*（QR086）. For the training, shall be conducted according to the *Training Management Procedure* (QR031). For the

document revision, shall be conducted according to the *Document Control Procedure* (QP000).

4.4 原物料不合格处理实施

Implementation of handling raw material nonconformities

4.4.1 质量部将处置完毕的 QP200-RE-01《不合格品处理报告单》分发到相关部门。

The Quality Department shall distribute the handled *Nonconformity Handling Report* (QP200-RE-01) to interested departments.

4.4.2 将需以信息反馈单形式反馈供应商的，将 QP110-RE-04《供方质量信息反馈单》发给采购，由采购发给供应商，采购将供应商回复的结果反馈给质量部，具体按照 QP110《采购控制程序》执行。

For nonconformities required to feed back to the supplier in the manner of the information feedback, the *Supplier's Quality Information Feedback* (QP110-RE-04) shall be sent to the Purchasing Department. Then the Purchasing Department shall send the feedback to the supplier. Also, the Purchasing Department shall feed back the supplier's reply to the Quality Department, which shall be conducted according to the *Purchasing Control Procedure* (QP110).

4.5 原物料不合格结果验证

Verification of the result of raw material nonconformities

质量部负责不合格品的处理执行情况的跟踪，并将结果及相关记录编号记录在 QP200-RE-01《不合格品处理报告单》中；启动 CAPA 和供方质量信息反馈单，后续的措施和效果确认在 QP220-RE-01《纠正预防措施报告单》和 QP110-RE-04《供方质量信息反馈单》上进行。

The Quality Department shall take charge of tracing the implementation of the nonconformity handling and record the result and relevant record number in the *Nonconformity Handling Report* (QP200-RE-01). Also, the Quality shall initiate CAPAs and the supplier's quality information feedbacks and complete the subsequent measures and effectiveness confirmation in *Report of Corrective and Preventive Action* (QP220-RE-01) and *Quality Feedback to Supplier No.*(QP110-RE-04).

5． 不合格半成品、成品的控制 Control of Nonconforming Semi-Finished Products and Finished Products

5.1 半成品、成品不合格的报告

Report of semi-finished product and finished product nonconformities

5.1.1 生产部在生产过程中发现半成品不合格，应首先对不合格品进行标识、隔离，当出现以下情形之一时，应填写 QR204-RE-01《生产异常单》，并通知质量部 QA：

Semi-finished products found in the manufacturing process shall be identified and separated by the Manufacturing Department. A *Manufacturing Deviation Form* (QR204-RE-01) shall be completed and the nonconformities shall be given notice to QA of the Quality Department when the following conditions occur.

a、 当数量、比例或严重程度超出标准范围时

Quantity, proportion or severity is out of the reference ranges;

b、 不合格类型以往从未出现过的

The types of nonconformities have never occurred before.

除上述情况的其他情形，不合格品由生产部统一收集后向质量部 QA 申请不合格证，由质量部 QA 授权生产部贴上不合格证后退回仓库。

For others apart from the mentioned conditions, nonconforming products shall be harmoniously collected by the Manufacturing Department. A “Disqualification Certificate” shall be applied to QA of the Quality Department and QA shall empower the Manufacturing Department to paste the “Disqualification Certification” on the nonconforming products. Finally, the nonconforming products with “Disqualification Certificate” shall be returned to the warehouse.

5.1.2 质量部 QC 检验过程中发现的不合格，应首先对不合格品进行标示，填写 QP200-RE-01《不合格品处理报告单》中的 Section A；并通知生产部/仓库对不合格品进行隔离。

Nonconforming products found in the QC inspection process of the Quality Department shall be identified at first. And concerned information shall be completed in the Section A of the *Nonconformity Handling Report* (QP200-RE-01). Also, the Manufacturing Department or Warehouse shall be informed to physically separate the nonconforming products.

5.1.3 对于从顾客处退回的产品，质量部 QC 在检验过程中发现不合格，应首先对不合格品进行标识，并填写 QP200-RE-01《不合格品处理报告单》中的 Section A，通知仓库对不合格品进行隔离。

For the products returned from the customers, nonconforming products found in the QC inspection process of the Quality Department shall be identified at first. And involved information shall be completed in the Section A of the *Nonconformity Handling Report* (QP200-RE-01). Also, the Warehouse shall be informed to physically separate the nonconforming products.

5.2 半成品、成品不合格的原因调查

Cause investigation of semi-finished product and finished product nonconformities

5.2.1 质量部 QA 接到相关的不合格报告后，组织对不合格原因进行调查分析，其它相关部门应协助质量部进行调查分析。同时依据附表 1《风险评估表》进行风险评估，评估结果为高的，需启动 CAPA 进行改进，风险为低或中的，依据不合格的具体情况确定是否启动 CAPA；启动后应将 CAPA 单号记录在相应的报告单中，以便于跟踪。CAPA 的操作依据 QP220《纠正和预防措施控制程序》进行。

With the assistance of other interested divisions, QA of the Quality Department shall organize to investigate and analyze the causes of nonconformities after getting the relevant nonconforming reports. Meanwhile, the risk evaluation shall be performed according to *Appendix 1 Risk Evaluation Form*. A CAPA shall be initiated to improve

the nonconformity if the result of the risk evaluation is high. However, whether a CAPA is necessary to open or not shall be determined according to the specific conditions of the nonconformities when the result of the risk evaluation is low or medium. The opened CAPA number shall be recorded in the corresponding report for the traceability. The operation of CAPA shall be conducted according to the *Corrective and Preventive Action Control Procedure* (QP220).

5.2.2 成品性能不合格调查过程中，应确认使用在此批成品中的半成品是否用到了其他的成品批号中，若有，需确认该批半成品的功能性状况；

During the investigation process of a finished product's performance nonconformity, whether the semi-finished products composing this lot of finished products have been used in other finished product lots shall be confirmed. If have, the functional conditions of this lot of semi-finished products shall be confirmed.

a) 若半成品合格，则使用了同一半成品的其他批号的成品无须确认，只需对此不合格批成品进行调查分析，调查出的原因如涉及到其他批号的产品时，应一并处理；

If the semi-finished products are qualified, it's required to investigate and analyze this lot of nonconforming finished products instead of confirming other lots of finished products using the same lot of semi-finished products. Other lots of products shall be handled together if the investigated causes show any involvements of them.

b) 若半成品不合格，则需对使用了同一半成品的所有其他批号的成品的留样进行确认，留样合格的，则无须对其进行追溯，留样不合格的，则需对所有不合格的成品批号进行处理。

If the semi-finished products are disqualified, the reserved samples of all finished product lots using the same lot of semi-finished products shall be confirmed. Traceability is not required if the reserved samples are qualified. While all nonconforming finished product lots are required to handle if the reserved samples are disqualified.

5.3 半成品、成品不合格的处置

Handling of semi-finished product and finished product nonconformities

5.3.1 质量部通过对不合格原因的调查、评估及风险分析的结果，作出最终处理结论，涉及成品不合格时，可组织相关部门进行评审。

Based on the investigation and evaluation of the nonconforming causes as well as the result of the risk analysis, the Quality Department shall give a final handling conclusion and organize interested divisions to review when involving finished product nonconformities.

5.3.2 生产（包括返工）过程中产生的废标签、废打码袋由生产部填写 QR202-RE-02《报废记录单》，在 QA 签字确认并监督下作报废处理；在下述情况下，由质量部负责人批准后按 QR202《物料处理程序》作报废处理：

Rejected labels and pouches generated during the manufacturing process (including rework) shall be scrapped by the Manufacturing Department with *Warehousing / Scrap Record* (QR202-RE-02) under the supervision of QA with the confirmation of a signature. The following conditions shall be scrapped after the approval of the

principal of the Quality Department according to the *Material Handling Procedure* (QR202).

a、 半成品、成品超过有效期的

Semi-finished products and finished products out of date;

b、 不合格半成品试剂条

Nonconforming semi-finished reagent strips;

c、 客户退回的不合格产品（包括召回的产品）

Nonconforming products returned from the customers (including recalled products).

5.3.3 不合格半成品、成品处置方式

Handling methods of nonconforming semi-finished products and finished products

a、 成品、半成品禁止让步接收；

Concession for finished products and semi-finished products is prohibited.

b、 返工：经相关部门评审后认为返工处理后可能得到合格品的可以依照 QR200《返工程序》执行，并将返工单号记录在 QP200-RE-01《不合格品处理报告单》上；

Rework shall be conducted according to the *Rework Procedure* (QR200) and the rework form number shall be recorded in the *Nonconformity Handling Report* (QP200-RE-01).

c、 研发使用：当不合格品不能用于生产时，如经过评审认为有研究试验价值，不合格品可由研发领出使用，但保留原不合格证，防止混入正常产品；

R&D use: nonconforming products which can't be used for manufacturing can be taken by R&D for usage after being reviewed valuable to R&D tests, but the "disqualification certificate" shall be kept to prevent mixing with authentic products;

d、 组件拆分后分别以原批号退回半成品仓库；

Separated components shall be respectively returned to the semi-finished storage in the name of the initial lots;

e、 报废：依照 QR202《物料处理程序》执行，并将报废单号记录在 QP200-RE-01《不合格品处理报告单》;

Scrap shall be conducted according to the *Material Handling Procedure* (QR202) and the scrap form number shall be recorded in the *Nonconformity Product Handling Report* (QP200-RE-01).

f、 其它：按 4.3.4 项执行。Others: according to the 4.3.4 execution.

5.4 不合格半成品、成品处理的实施

Implementation of nonconforming semi-finished product and finished product handling

质量部负责将处理措施填写完 Section A~C 的 QP200-RE-01《不合格品处理报告单》抄送至相关部门，由

各部门按处理意见实施对不合格品的处置。

The Quality Department shall complete the Section A, B and C of the *Nonconformity Handling Report* (QP200-RE-01) and send it to the interested departments. While each involved department shall implement the handling to the nonconforming products according to the suggestions.

5.5 结果验证

Result verification

质量部负责不合格品的处理执行情况的跟踪，并将结果及相关记录编号记录在 QP200-RE-01《不合格品处理报告单》中。如启动 CAPA，后续的措施和效果确认依据 QP220《纠正和预防措施控制程序》进行。

The Quality Department shall take charge of tracing the implementation of the nonconforming product handling and record the result and relevant record number in the *Nonconformity Handling Report* (QP200-RE-01). If a CAPA is initiated, the subsequent actions and effectiveness shall be according to *Corrective and Preventive Action Control Procedure* (QP220).

6 不合格品处理报告单的管理 Management of Nonconforming Product Handling Report

6.1 质量部对各不合格品处理报告单进行统一编号，以便于对不合格的统计分析。

The Quality Department shall harmoniously number each nonconforming product handling report so as to statistically analyze them conveniently.

6.2 编号由两位大写英文字母和七位数字组成，七位数字前四位表示年份（2 位）、月份（2 位），最后三位表示顺序号。两位大写英文字母如下：

The numbers shall be made of two digits of capitalized English letters and seven digits of Arabic numerals whose front four digits stand for the year (2 digits) and the month (2 digits) and the last three digits stand for the serial number. The two capitalized English letters are as follows:

a. YB 表示原辅料的不合格

   YB stands for raw material nonconformities;

b. CB 表示半成品/成品的不合格

   CB stands for semi-finished product or finished product nonconformities.

6.3 不合格品统计和趋势分析

Statistics and trend analysis of nonconforming products

质量部每月按《数据分析、应用程序》(QP210）对过去十二个月的不合格品、不合格品率分别进行统计，并进行趋势分析，分析的结果若表明有不良趋势时，应制定计划，采取相应的改进、纠正和预防措施。

According to the *Data Analysis and Application Procedure* (QP210), the Quality Department shall respectively summarize the nonconforming products and nonconforming rates of the past 12 months each month and analyze their

trends as well. Plans shall be established and relevant improvements and CAPAs shall be taken when the analysis results show adverse trends.

6.3.1 一个月内同一责任部门非性能类成品不合格出现 3 起或 3 起以上。

Non-performance nonconformities of finished products resulting from the same department are more than 3 (3 included) within a month.

6.3.2 一个月内同一类产品相同类型性能类成品不合格出现 3 起或 3 起以上。

The same performance nonconformities of the same finished products are more than 3 (3 included) within a month.

6.3.3 一个月内同一责任部门引起的进料不合格出现 5 起或 5 起以上。

Incoming nonconformities resulting from the same department are more than 5 (5 included) within a month.

6.3.4 一个月内同一供应商同一类物料的不合格出现 5 起或 5 起以上。

The same material nonconformities of the same supplier are more than 5 (5 included) within a month.

6.3.5 连续 5 个月出现合格率下降。

The qualified rates continuously drop in 5 months.

6.3.6 连续 2 个季度出现成品不合格率超标。

Defect rates are continuously out of the ranges in 2 quarters.

6.4 不合格清单

Nonconformity list

不合格清单必须包括不合格发生日期、不合格单号、批号、品名、数量、项目、不合格描述、原因、不合格处理、处理日期、不合格跟踪、纠正预防措施（若有）。质量部负责建立和定期更新不合格清单。

The nonconformity list shall include the date when the nonconformity occurs, the form number of the nonconformity, batch code, product name, quantity, project, nonconformity description, causes, nonconformity handling, handling date, nonconformity traceability and CAPA (if have). The Quality Department is responsible for establishing and regularly updating the nonconforming list.

7、相关文件 Relevant Documents

7.1《监视和测量装置控制程序》QP160 *Monitoring and Measuring Apparatus Control Procedure*

7.2《数据分析、应用程序》QP210 *Data Analysis and Application Procedure*

7.3《纠正和预防措施控制程序》QP220 *Corrective and Preventive Action Control Procedure*

7.4《生产异常处理操作程序》QR204 *Manufacturing Deviation Handling and Operation Procedure*

7.5《返工程序》QR200 *Rework Procedure*

7.6《采购控制程序》QP110 *Purchasing Control Procedure*

7.7《物料处理程序》QR202 *Material Handling Procedure*

7.8《更改评估程序》QR086 *Change Assessment Procedure*

7.9《更改控制程序》QP090 *Change Control Procedure*

7.10《培训管理程序》QR031 *Training Management Procedure*

7.11《文件控制程序》QP000 *Document Control Procedure*

8、 质量记录 Quality Records

8.1《不合格品处理报告单》(QP200-RE-01) *Nonconformity Handling Report*

8.2《让步接收申请单》(QP200-RE-02) *Concession Application Form*

附件 1《风险评估表》

Appendix 1 *Risk Evaluation Form*

使用下列三个表格来判定风险的等级：

The following three tables are used to determine the risk level:

1. 使用表 A 评估严重程度
   Table A is used to evaluate the severity.
2. 使用表 B 评估发生概率
   Table B is used to evaluate the probability of occurrence.
3. 根据严重程度及概率程度来判定风险等级。
   Table C is used to determine the risk level according to the severity and probability of occurrence.

表 A Table A

严重程度 Severity	**说明 Explanation**
严重的 Serious	产品性能受到影响，且： Affect the product performance, and ● 直接导致使用者/病人死亡或健康严重损害，或 Directly lead to the user or patient's death or terribly damaged health, or ● 会产生不正确的信息（比如出错的或损坏的数据），从而造成使用者/病人死亡或健康严重损害。 Generate inaccurate information (if incorrect or corrupted data) which leads to the user or patient's death or terribly damaged health.
中度的 Minor	产品性能受到影响，且： Affect the product performance, and ● 直接对使用者/病人造成可逆的和/或暂时的伤害，或 Directly lead to curable and or temporary injuries to the user or patient, or ● 会产生不正确的信息（比如出错的或损坏的数据），从而对使用者/病人造成可逆的和/或暂时的伤害。 Generate inaccurate information (if incorrect or corrupted data) which leads curable and or temporary injuries to the user or patient.
微小的 Negligible	只是产品性能受到影响，不会对使用者/病人造成任何伤害。 Only affect the product performance and no injuries to the user or patient.

表 B Table B

发生概率 Probability of Occurrence	**说明 Explanation**
很可能的 Frequent	最近两年，同类产品相同类型不合格发生 5 起以上 The same type nonconformities of the same product are more than 5 during the recent two years.
偶尔的 Occasional	最近两年，同类产品相同类型不合格发生 3~4 起 The same type nonconformities of the same product are 3 to 4 during the recent two years.
罕见的 Rare	最近两年，同类产品相同类型不合格发生 1~2 起 The same type nonconformities of the same product are 1to 2 during the recent two years.

表 C Table C

发生概率 **Probability of Occurrence**	**严重程度** **Severity**		
	严重的 Serious	中度的 Minor	微小的 Negligible
很可能的 Frequent	高 High	高 High	高 High
偶尔的 Occasional	高 High	中 Medium	低 Low
罕见的 Rare	中 Medium	低 Low	低 Low

文件更改履历

Document History Summary

修改后版本或 页码修改号 Updated Version Or Page Revision	更改单 编号 DCR Ref	更改概述 Summary of Changes	生效日期 Effective Date