Risk Management Report

COVID-19 Antigen Rapid Test Kit (Swab)

Version 1.0

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1. The introduction of product

The COVID-19 Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab or nasopharyngeal swab specimens.

SARS-CoV-2 specific antibodies are immobilized onto the test region of the membrane and combined with other reagents/pads to construct a test strip.

During testing, the specimen reacts with anti-COVID-19 antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the reagents in test line region. Therefore, if the specimen contains COVID-19 antigen, a colored line will appear in test line. If the specimen does not contain COVID-19 antigen, no colored line will appear in the test line regions, indicating a negative result. To serve as a procedural control, a blue colored line will always appear in the control line region, and the blue color will change from blue to red during testing indicating that the proper volume of specimen has been added and membrane wicking has occurred.

2. The Plan of Risk Management and implementation

This project began in Jul, 2020. At the same time, we made a risk management plan. We formed a risk management team and identified the project's risk management director to ensure that the project's risk management activities are effectively implemented according to the risk management plan.

3. Participant departments and personnel

Name	Department	Position
Wei Lihua	R&D	Team leader
Zhen Caiwen/Ju lingjun/Lin zi	R&D	Member
Wu yaxin/Jin XiaoYan/Cheng chun	Manufacture Dept.	Member
Yu XinyingLi Chuanhuan/Liu Zhejun	QA&QC	Member
Qian dandan	Sales Department	Member

4. Applicable Standards

EN ISO 14971:2019 Medical devices — Application of risk management to medical devices

5. Questions that can be used to identify medical device characteristics that could impact on safety.

According to the requirements of the plan and the standard EN ISO 14971:2019, we analyzed the safety characteristics of (Whole Blood/Plasma/Serum)，and recorded as follows: Please see attachment 1

6. **Initial hazard analysis (PHA, including foreseeable sequence hazards，hazardous situations and possible damages) and the control scheme of initial risk**

According to the list of the safety characteristics, we summarize the initial hazard analysis table, and the corresponding risk control scheme is determined as follows. Please see attachment 2

7. Hazard analysis and critical control points (HACCP)

7.1 Risk evaluation: The team members analyzed the probability and severity level of the hazard by risk analysis according to the requirements of the plan and the standard EN ISO 14971:2019.

7.2 The acceptable criteria for risk management is as follows.

7.2.1Severity levels of damage

Common terms	Mark	Definition of risk
Minor	S1	Slight injury or no injury.
Moderate	S2	moderate injury
deadly	S3	One person is killed or seriously
Catastrophic	S4	Many people are killed or seriously

7.2.2Probability levels of damage

Common terms	Mark	Frequency (per year)
precious Little	P1	$<10^{-6}$
Improbable	P2	10^{-4}-10^{-6}
Remote	P3	10^{-2} -10^{-4}
Occasional	P4	10^{-1}-10^{-2}
Probable	P5	1-10^{-1}
Frequent	P6	>1

7.2.3Risk assessment criteria

Probability levels of damage		Severity levels of damage			
		S4	S3	S2	SI
		Catastrophic	Deadly	Moderate	Minor
Frequent	P6	U	U	U	R
Probable	P5	U	U	R	R
Occasional	P4	U	R	R	R
Remote	P3	R	R	R	A
Improbable	P2	R	R	A	A
Precious Little	P1	A	A	A	A

7.3 We make risk assessments before or after the disaster reduction， and the results are as follows. Please see attachment 3.

8. Conclusion

According to the risk analysis, risk assessment and risk control of the product, we can confirm that the risk of the product has been effectively managed and controlled within acceptable limits.

Attachment 1：

Questions that can be used to identify medical device characteristics that could impact on safety

According to the requirements of the plan and the standard EN ISO14971:2012，we analyzed the safety characteristics of The COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Plasma/Serum)，and recorded as follows:

Question	The determination of characteristics	Possible hazard
C.2.1 What is the intended use and how is the medical device to be used?	The COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Plasma/Serum) is a qualitative membrane-based immunoassay for the detection of NCoV-19 antibodies in whole blood, serum, or plasma.	Information hazard
C.2.2 Is the medical device intended to be implanted	NO, this product is not implanted medical device.	NO NO
C.2.3 Is the medical device intended to be in contact with the patient or other persons?	NO, this product is an in vitro diagnostic reagent, and it is not in contact with the patient or other persons?	NO
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	No, this product is not used with the medical device, and it is not in contact with patients	NO
C.2.5 Is energy delivered to or extracted from the	No, this product has no energy input and output.	NO

patient?		
C.2.6 Are substances delivered to or extracted from the patient ?	Yes, the test samples are extracted from the patients.	biological hazard and chemical hazard
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No, this product is a disposable product.	NO
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No, this product is a non-sterile product, and it don't need to sterilize	NO
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	No, this product does not need to clean and disinfect by users.	NO
C.2.10 Is the medical device intended to modify the patient environment?	No, This product has no effect on the patient's environment.	NO
C.2.11 Are measurements taken?	Yes, This product is a qualitative detection reagent.	NO
C.2.12 Is the medical device interpretative?	No	NO
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines	No, this product can be used alone.	NO

or other medical techNologies?		
C.2.14 Are there unwanted outputs of energy or substances?	No, this produce has no energy or substance output	NO
C.2.15 Is the medical device susceptible to environmental influences?	No	NO
C.2.16 Does the medical device influence the environment?	Yes, this product is disposable. Improper disposal may affect the environment.	Information hazard Improper identification of post processing.
C.2.17 Are there essential consumables or accessories associated with the medical device?	No	NO
C.2.18 Is maintenance or calibration necessary?	NO, this product does not require maintenance and calibration.	NO
C.2.19 Does the medical device contain software?	No, this product does not contain software?	NO
C.2.20 Does the medical device have a restricted shelf-life?	Yes, the restricted shelf-life of this product is 2 years.	Information hazard Improper identification
C.2.21 Are there any delayed or long-term use effects?	No, this product is disposable.	NO
C.2.22 To what mechanical forces will the medical device be subjected?	No, this product does not subject any mechanical force.	NO
C.2.23 What determines the lifetime of the medical device?	The damage of the packaging material or aging determine the lifetime of the product.	environmental hazard Improper storage condition

C.2.24 Is the medical device intended for single use?	Yes, this product is disposable.	Information hazard The logo is Not clear and easy to understand.
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	Yes, the waste should be disposed in the proper way after use.	Using hazard disabler
C.2.26 Does installation or use of the medical device require special training or special skills?	No, this product does not need to be installed.	NO NO
C.2.27 How will information for safe use be provided?	The product specification details the safe use of information.	Information hazard The logo is Not clear and easy to understand.
C.2.28 Will new manufacturing processes need to be established or introduced?	NO	NO
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface?	Yes, The user shall follow the product instructions to operate and interpret.	Information hazard The logo is Not clear and easy to understand.
C.2.29.1 Can the user interface design features contribute to use error?	Yes, The operator may ignore the warning signs. The sample is not added to the sample window or the product is placed in the sample over the sample level warning line.	Using hazard Incorrect results.
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	No	NO

C.2.29.3 Does the medical device have connecting parts or accessories?	No, this product does not have any connecting parts or accessories?	NO
C.2.29.4 Does the medical device have a control interface?	No, this product does not have any control interfaces.	NO
C.2.29.5 Does the medical device display information?	Yes, the measurement results are judged by the color of the display line.	Using hazard Incorrect results.
C.2.29.6 Is the medical device controlled by a menu?	NO	NO
C.2.29.7 Will the medical device be used by persons with special needs?	NO	NO
C.2.31 In what way(s) might the medical device be deliberately misused?	NO	NO
C.2.32 Does the medical device hold data critical to patient care?	NO	NO
C.2.33 Is the medical device intended to be mobile or portable?	Portable. The individual packaging product can be independently provided with function,and it is easy to carry.	NO
C.2.34 Does the use of the medical device depend on essential performance?	Yes, if the product fails, the function can not be realized.	NO

Attachment 2：

Initial hazard analysis (PHA, including foreseeable sequence hazards，hazardous situation and possible damage) and the control scheme of initial risk

According to the list of the safety characteristics, we summarize the initial hazard analysis table, and the corresponding risk control scheme is determined as follows.

The type of harm	Predictable events and sequence of events	The influence of harm	Possible damage.	Preliminary control measures
Biological hazard and chemical hazard	The qualities of raw materials that make up the product are not qualified.	Affect the accuracy of the product.	Information hazard	To strictly implement 《The control procedures of procurement》
Environment hazard	1.Dust particles in clean area are out of limits Temperature and humidity can not meet the requirements. 2.The warehouse environment can not meet the requirements.	Affect the accuracy of the product.	Information hazard	To strictly implement 《The control procedures of production work environment and clean sanitation》 、《The control procedures of product protection》
Information hazard	The identifications on the product are not defined, clear or inaccurate.	Users can't get the real results.	Information hazard	To Strictly follow the relevant procedures to ensure that the product identifications are accurate .
	The protective measures on the package are not clearly defined or clear.	Patients may use products that are not available.	The products lose efficacy or draw incorrect conclusions.	To Strictly implement 《the Management regulations of Medical device instructions, labels and packaging labellings》
	The attentions and the operation steps in the instruction are described tedious, unclear to	The operator cannot use the product properly.	The operator cannot use the product	

	unstand or incomplete			
Using hazard and disabler	Do not pay attention to the instructions and illustrations, so the product cannot be expected to be used or the product's rapid accuracy is invalid.	The product cannot be expected to be used and it may cause users to delay time or draw incorrect conclusions.	It may Waste products, mislead users, or may cause other chain effects.	To Strictly implement 《 the Management regulations of Medical device instructions, labels and packaging labellings 》 , Corresponding inspection procedures and technological process . To carry out strict installation ,operation and performance verification for production equipment.

Attachment 3：

Hazard analysis and critical control points (HACCP) for COVID-19 Antigen Rapid Test Kit (Swab)												
Hazard	**Risk assessment before disaster reduction.**					**risk control measures**	**Risk assessment after disaster reduction.**					**Program**
	Negative factor	**Cause**	**Definition of risk**		**Risk evaluation**		**Definition of risk**		**Risk evaluation**	**The creation of any new risk**	**Balance between Risk and Benefit**	
			Peverity levels	**Probability levels**			**Severity levels**	**Probability levels**				
Using Design:												
Inconsistent (false negative/false positive) results.	Users/patients need medical guidance.	Incorrect design input requirements.	Serious	Occasional	Unacceptable	Design input review and feasibility study.	Serious	Almost impossible	Acceptable	YES[ ] NO [√]	Benefit > Risk	1
		The key raw materials (antibodies and recombinant antigens) do not produce the intended performance.	Serious	Occasional	Unacceptable	The key raw materials (antibodies and recombinant antigen)should be adequately validated during the design control phase.	Serious	Almost impossible	Acceptable	YES[ ] NO [√]	Benefit > Risk	2
		Cross reaction and interfering substance	Serious	Occasional	Unacceptable	Sufficient interference verification should be carried out during the design control phase.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	3
		Interference caused by different types of samples.	Serious	Possible	Unacceptable	Sufficient interference verification should be carried out during the design control phase.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	4
		The operation of the product exceeds the specified environmental conditions.	Serious	Remote	Unacceptable	The environmental conditions of the experiment are clearly stated in the instructions.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	5
		Lack of adequate shelf life and storage conditions.	Serious	Occasional	Unacceptable	The real stability experiment is carried out during the design control phase，and the product storage conditions are clearly stated in the instructions.	Serious	Almost impossible	Acceptable	YES[ ] NO [√]	Benefit > Risk	6
		Raw material storage condition is not correct.	Serious	Remote	Unacceptable	Store raw materials according to supplier COA	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	7
		The intended use of the product is not sufficient.	Serious	Occasional	Unacceptable	Sufficient validation is performed in the design control phase and state the relevant information clearly in the instructions.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	8

		The operation of the product exceeds the specified reading time.	Serious	Remote	Unacceptable	Clearly state the reading time in the instructions.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	9
Reagent production												
Inconsistent (false negative/false positive) results.	Users/patients need medical guidance.	The specification of key raw materials (recombinant antigens and antibodies) is not confirmed.	Serious	Remote	Unacceptable	Key raw materials (recombinant antigens and antibodies) are tested before being used for production.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	10
		The specification of sample pad is not confirmed.	Serious	Occasional	Unacceptable	Control risks by incoming inspection, production process control and semi-finished inspection.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	11
		The specification of nitrocellulose membrane is not confirmed.	Serious	Remote	Unacceptable	Control risks by incoming inspection, production process control and semi-finished inspection.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	12
		The storage condition of raw materials is not correct.	Serious	Remote	Unacceptable	The storage condition of raw material is reflected in the supplier's raw material technical specification, and the raw material is stored according to the specification.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	13
		The desiccant is invalid or absent.	Serious	Occasional	Unacceptable	Control risks by incoming inspection and production process control.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	14
		Incorrect QC sample usage and improper QC procedure.	Serious	Occasional	Unacceptable	Training inspection procedures to control risks.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	15
		Labels are changed or missing,and the specification is error.	Serious	Remote	Unacceptable	Control risk by SOP and product inspection.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	16
		Improper packing (pollution and/or damage)	Serious	Remote	Unacceptable	Control risks by product inspection	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	17
		Improper test strip assembly.	Serious	Occasional	Unacceptable	Control risk by production documentation and deviation, process control, and finished-product inspection.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	18

		Incorrect planning	Serious	Occasional	Unacceptable	Control risk by production documentation and deviation, process control, and finished-product inspection.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	19
		Improper production conditions	Serious	Remote	Unacceptable	Control risks by the work area control procedure.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	20
		Improper storage conditions of the semi-finished and finished products	Serious	Remote	Unacceptable	Control risk by warehouse management procedures.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	21
		Unskilled/untrained staff to produce.	Serious	Remote	Unacceptable	Conduct appropriate training for production staff and keep track of training records	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	22
		The equipment parameters are not reliable.	Serious	Remote	Unacceptable	Perform equipment validation at regular intervals	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	23
False negative	Users/patients need medical guidance	Reproducibility	Serious	Remote	Unacceptable	Control risk by controlling production documents and personnel, incoming inspection of key raw materials, sampling scheme of semi-finished or finished products	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	24
		Repeatability	Serious	Remote	Unacceptable	Control risk by controlling production documents and personnel, incoming inspection of key raw materials, sampling scheme of semi-finished or finished products	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	25
Can not run	Users need additional tests	Nitrocellulose membrane is damaged	Serious	Remote	Unacceptable	Control risk by production process control	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	26
		Lack of sample pad and polyester	Serious	Remote	Unacceptable	Control risk by production process control	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	27
Out of use		Absence of instruction	Serious	Remote	Unacceptable	Control risk by production control, product inspection	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	28
	Users/patients need medical guidance	Improper plastic template.	Negligible	Possible	acceptable	Control risk by incoming inspection	Negligible	Occasional	Acceptable	YES[ ] NO [√]	Benefit > Risk	29
	Users need	The firmness of plastic template is insufficient	Negligible	Possible	acceptable	Control risk by incoming inspection	Negligible	Occasional	Acceptable	YES[ ] NO [√]	Benefit > Risk	30

	additional tests	The plastic template is damaged.	Negligible	Possible	acceptable	Control risk by incoming inspection	Negligible	Occasional	Acceptable	YES[ ] NO [√]	Benefit > Risk	31
Reagent storage and transportation												
False negative	Users/patients need medical guidance	Improper transport storage conditions	Serious	Occasional	Unacceptable	Carry out transportation research to control risks.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	32
False negative		Improper transport storage conditions	Serious	Occasional	Unacceptable	Carry out transportation research to control risks.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	33
out of use	Users need additional tests	The packing bag is destroyed or the reagent is damaged	Serious	Occasional	Unacceptable	Carry out transportation research to control risks.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	34
Use of reagents												
Inconsistent (false negative/false positive) results	Users/patients need medical guidance	The reagent strips are used or dirty.	Serious	Remote	Unacceptable	The relevant information is clarified in the instruction	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	35
		The operator does not follow the operation steps	Serious	Occasional	Unacceptable	The relevant information is clarified in the instruction	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	36
		Error handling during sample collection	Serious	Occasional	Unacceptable	The relevant information is clarified in the instruction	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	37
Inconsistent (false negative/false positive) results	Users/patients need medical guidance	Incorrect sample type.	Serious	Occasional	Unacceptable	The relevant information is clarified in the instruction	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	38
		Sample is polluted (container not clean)	Serious	Occasional	Unacceptable	The relevant information is clarified in the instruction	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	39
		Insufficient or excessive use of samples	Serious	Occasional	Unacceptable	Sufficient verification of sample quantity is carried out in the design control phase.The relevant information is clearly presented in the instruction.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	40
		related issues with sample stability	Serious	Occasional	Unacceptable	Sufficient verification is carried out in the design control phase.The relevant information is clearly presented in the instruction.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	41
		The storage conditions of product are not correct.	Serious	Possible	Unacceptable	Sufficient verification is carried out in the design control phase.The relevant information is clearly presented in the instruction.	Serious	Remote	Acceptable	YES[ ] NO [√]	Benefit > Risk	42
		The environmental temperature of the sample is too high or too low.	Negligible	Possible	acceptable	Sufficient verification of sample elastic temperature is carried out in the design control phase.The relevant information is clearly presented in the instruction.	Negligible	Remote	Acceptable	YES[ ] NO [√]	Benefit > Risk	43

		Reagent pollution caused by finger contact.	Negligible	Possible	acceptable	The correct detection process is described in the instruction.	Negligible	Remote	Acceptable	YES[ ] NO [√]	Benefit > Risk	44
incorrect reading	Users/patients need medical guidance	The read time is not noted in the instruction	Serious	Occasional	Unacceptable	The relevant information is clearly presented in the instruction.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	45
		There is no explanation of the result in the instruction.	Serious	Occasional	Unacceptable	The relevant information is clearly presented in the instruction.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	46
		The results of T line and C line are confused.	Serious	Occasional	Unacceptable	The relevant information is clearly presented in the instruction.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	47
can not run	The user needs another reagent.	Inadequate sample	Serious	Possible	Unacceptable	Sufficient verification of sample quantity is carried out in the design control phase.The relevant information is clearly presented in the instruction.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	48
Appearance defects	The user is not satisfied with the appearance of the product.	The plastic template is damaged at assembly process	Negligible	Occasional	acceptable	Inspection procedures and production process control procedures are used to control the risk.	Negligible	Occasional	Acceptable	YES[ ] NO [√]	Benefit > Risk	49
The failure of external control	Users need other diagnostics	External control is not appropriate	Serious	Occasional	Unacceptable	The relevant information is clearly presented in the instruction.It is recommended that customers should use effective diagnostic methods.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	50
Users and bystanders are polluted.	Health risk	The user is polluted by the sample during.or after the use of sample	Serious	Remote	Unacceptable	Any potential hazardous substances are present in the instruction to warn users.The used reagent should be discarded in the proper biological dustbin.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	51
		Biochemical pollution during the experiment	Serious	Remote	Unacceptable	Any potential hazardous substances are present in the instruction to warn users.The used reagent should be discarded in the proper biological dustbin.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	52

		Animal source material and test samples will pollute others in the treatment of used reagents	Serious	Remote	Unacceptable	The user can know biological material that exists in the reagent by the instruction .There are no infectious antigens or antibodies.The used reagent should be discarded in the proper biological dustbin.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	53
Environmental hazard	Health risk	Discard reagents containing BSA, antigens, and antibodies.	Serious	Occasional	Unacceptable	About the condition of reagent rejection， the hint has been given in the user instructions.There are no infectious antigens or antibodies..Antibodies, antigens and BSA are present in the membrane with low concentrations and dry conditions.	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	54
		Non-recyclable plastic （plastic lining）	Negligible	Improbable	acceptable	The relevant information is clearly presented in the instruction.	Negligible	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	55
		Non-recyclable packaging, including used droppers and reagents.	Negligible	Improbable	acceptable	The relevant information is clearly presented in the instruction.	Negligible	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	56
Production and post-production information												
Can not identify hazards and/or hazardous situations	Information risk	There is no related documents or review system for medical device information collection established	Serious	Possible	Unacceptable	Establish a system of medical device information collection and review， and form a document.《 QSB-017 The control procedures of adverse event monitoring, reevaluation and advisory notification》、《 QSB-016 The control procedure of user feedback 》、《QSB-019 The control procedure of risk management》	Serious	Almost impossible	Acceptable	YES[ ] NO [√]	Benefit > Risk	57

Can not identify hazards and/or hazardous situations	Information risk	No information and update standards are collected.	Serious	Remote	Unacceptable	Establish a system of medical device information collection and review，and form a document.《QSB-017 The control procedures of adverse event monitoring, reevaluation and advisory notification》、《QSB-019 The control procedure of risk management》	Serious	Improbable	Acceptable	YES[ ] NO [√]	Benefit > Risk	58
	Information risk	No effective public information of similar products on the market. is collected or reviewed	Serious	Possible	Unacceptable	《QSB-017 The control procedures of adverse event monitoring, reevaluation and advisory notification》《QSB-019 The control procedure of risk management》	Serious	Almost impossible	Acceptable	YES[ ] NO [√]	Benefit > Risk	59
	Risk is out of control	There is no assessment of possible security issues.	Serious	possible	Unacceptable	《QSB-017 The control procedures of adverse event monitoring, reevaluation and advisory notification》、《QSB-019 The control procedure of risk management》	Serious	Almost impossible	Acceptable	YES[ ] NO [√]	Benefit > Risk	60