Risk Analysis and Management

according to EN ISO 14971:2012、ISO 13485:2016

Device: SARS-CoV-2 IgG/IgM Rapid Test

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1 Summary

1.1 Foreword

The purpose of this risk management is to determine the possible risks caused by the company's product SARS-CoV-2 IgG/IgM Rapid Test, and explain the necessary corresponding measures in order to control the risks. Acceptable level. Through risk management, the company can take appropriate measures to improve products and improve product quality.

This report is the risk management of our company's CE certified SARS-CoV-2 IgG/IgM Rapid Test. The report will determine all potential hazards and the potential causes of each hazard. Evaluate the degree of damage and the probability of occurrence of various hazards. For unacceptable risks, take necessary measures and estimate the residual risks after adopting the measures. Result: Through appropriate measures, the risks leading to the occurrence of various potential hazards have been reduced to acceptable levels, and the cumulative risk of the occurrence of various risks has been reduced to acceptable levels.

1.2 Product introduction

SARS-CoV-2 IgG/IgM Rapid Test is a product developed by Zhuhai Encode Medical Engineering Co.,Ltd.

1.3 Implementation of risk management

According to the requirements of EN ISO 14971: 2012, the company planned the risk activities for SARS-CoV-2 IgG/IgM Rapid Test products and formulated a risk management plan.

The risk management plan determines the acceptable criteria for risk, and arranges the requirements for reviewing risk management activities during product design and development, the responsibilities and authorities of personnel involved in risk management activities, and methods of obtaining production and post-production information.

The company formed a risk management team to determine the risk management responsible for the project. Ensure that the project's risk management activities are effectively performed in accordance with the risk management plan.

1.4 Risk management responsibilities and authority allocation

The company's general manager provides appropriate resources for risk management and assumes leadership responsibility for risk management. Ensure that the personnel assigned to the risk management, implementation and evaluation work are trained and qualified, and that the risk management performers have the appropriate knowledge and experience.

The R & D center is responsible for risk management activities in the product design and development process, forming relevant records of risk analysis, risk evaluation, risk control, and residual risk analysis, and preparing risk management reports.

The heads of the relevant departments such as the quality control department, sales department, procurement department, production department, etc. analyze all known and foreseeable hazards from the perspective of product realization, and collect and post-production information and timely feedback to the R & D center for risk assessment , If necessary, conduct a new round of risk management activities.

The R & D center and review team members regularly review the results of risk management activities and are responsible for their correctness and effectiveness. The R & D center is responsible for the organization of all risk management documents.

Table 1 Risk Management Review Team Staff Form

Staff	Department	Position	Duty
General manager	General manager's office	Team leader	Responsible for comprehensive guidance of the risk management process
Management representative	System office	Team member	Evaluate from a technical perspective
Technical director	R & D Center	Team member	Evaluate from a technical perspective
Manager of	Quality	Team member	Evaluate from inspection and quality

quality control department	control department		control perspectives
Regulatory commissioner	R & D Center	Team member	Evaluation from a regulatory perspective
Sales manager	Sales department	Team member	Collect customer needs and timely feedback market information
Purchasing manager	Purchasing department	Team member	Selecting quality raw material suppliers

1.5 Risk management plan

1.5.1 Scope of risk management activities

This risk management plan is mainly for the risk management activities of the SARS-CoV-2 IgG/IgM Rapid Test throughout its life cycle (including design and development, product realization, final decommissioning, and disposal).

1.5.2 Formulation of rights and duties

Table 2 Risk Management Review Team Staff Form

Staff	Department	Duty
Project manager	R & D Center	Responsible for the development of risk management plans
Project manager	R & D Center	Responsible for risk analysis and assessment
Inspection team leader	Quality control department	Responsible for risk control

For the composition and responsibilities of the risk management reviewers, see 1.4

1.5.3 Review of risk management activities

a.Verification that the risk management plan has been properly implemented

The members of the review team are responsible for verifying the implementation of the risk management plan, checking the risk analysis, risk assessment, and risk control by viewing the risk management documents to ensure that the risk management activities planned by the risk management plan have been properly implemented.

b. Effectiveness verification of risk management activities

The review team can verify the effectiveness of risk management by collecting clinical data and production and post-production information to ensure the effectiveness of risk management activities.

1.5.4 Criteria for ensuring risk acceptability according to the manufacturer's guidelines for determining risk acceptability.

1.5.5 Verification activity

a. Implementation of risk control measures in final design

The risk review team analyzed and checked the final design documents and production processes, and determined that the risk control measures formulated had been effectively implemented in every link of product design and production.

b. Implementing measures reduces risk

The risk assessment team shall analyze the implemented risk reduction measures and evaluate the effect of the implemented measures on risk reduction.

1.5.6 Activities to collect review-related production and post-production information

2 Risk Analysis

2.1 Judgment of intended use and safety-related characteristics of medical devices

Table 3 Feature analysis table

Question content	Feature judgment	Possible harm
C2.1 What is the intended use and how is the medical device to be used?	This product is used for the detection of coronavirus (COVID-19) IgG/ IgM , and guides patients to further detection and treatment based	NO

	on positive results. See the instruction manual for specific usage steps.	
C2.2 Is the medical device intended to be implanted?	NO	NO
C2.3Is the medical device intended to be in contact with the patient or other persons?	NO	NO
C2.4What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	This product is an in vitro diagnostic reagent. The raw materials are mainly antibodies, buffer salts, colloidal gold, PVC membrane and other materials. These materials are conventional raw materials, and their safety and related characteristics are known without danger.	NO
C2.5Is energy delivered to or extracted from the patient?	NO	NO
C2.6Are substances delivered to or extracted from the patient?	NO	NO
C2.7Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO	NO
C2.8Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO	NO
C2.9Is the medical device intended to be routinely cleaned and disinfected by the user?	NO	NO
C2.10Is the medical device intended to modify the patient environment?	NO	NO
C2.11Are measurements taken?	This reagent judges the results based on the color change during the detection process, and the results are easy to read. The accuracy of the measurement results is related to the operation process, and it is necessary to strictly follow	Inaccurate operation may cause false negatives or false positives.

	the operation steps of the instruction manual.	
C2.12Is the medical device interpretative?	NO	NO
C2.13Is the medical device intended for use in conjunction with other medical devices, Medicines or other medical technologies?	NO	NO
C2.14Are there unwanted outputs of energy or substances?	NO	NO
C2.15Is the medical device susceptible to environmental influences?	Store at 2 ℃ ~ 30 ℃ in a cool, dark place.	Improper storage temperature will affect the effectiveness of the product.
C2.16Does the medical device influence the environment?	Yes, improper waste disposal may affect the environment.	Environmental hazard
C2.17Are there essential consumables or accessories associated with the medical device?	NO	NO
C2.18Is maintenance or calibration necessary?	NO	NO
C2.19Does the medical device contain software?	NO	NO
C2.20Does the medical device have a restricted shelf-life?	The product is valid for 24 months.	Exceeding the validity period will affect the accuracy of the test results.
C2.21Are there any delayed or long-term use effects?	NO	NO
C2.22To what mechanical forces will the medical device be subjected?	NO	NO
C2.23What determines the lifetime of the medical device?	Temperature	High or low temperature outside 2 ℃ ~ 30 ℃ will affect the shelf life of the product.
C2.24Is the medical device intended for single use?	YES	Reuse results are incorrect.

C2.25Is safe decommissioning or disposal of the medical device necessary?	NO	NO
C2.26Does installation or use of the medical device require special training or special skills?	NO	NO
C2.27How will information for safe use be provided?	The product manual has detailed safe use information	Information hazard
C2.28Will new manufacturing processes need to be established or introduced?	NO	NO
C2.29Is successful application of the medical device critically dependent on human factors such as the user interface?	YES	The use of the product requires strict operation in accordance with the requirements of the instruction manual.
C2.29.1Can the user interface design features contribute to use error?	NO	NO
C2.29.2Is the medical device used in an environment where distractions can cause use error?	NO	NO
C2.29.3Does the medical device have connecting parts or accessories?	NO	NO
C2.29.4Does the medical device have a control interface?	NO	NO
C2.29.5Does the medical device display information?	NO	NO
C2.29.6Is the medical device controlled by a menu?	NO	NO
C2.29.7Will the medical device be used by persons with special needs?	NO	NO
C2.29.8Can the user interface be used to initiate user actions?	NO	NO
C2.30Does the medical device use an alarm system?	NO	NO
C2.31In what way(s) might the medical device be deliberately misused?	NO	NO
C2.32Does the medical device hold data critical to patient care?	NO	NO

C2.33s the medical device intended to be mobile or portable?	NO	NO
C2.24Does the use of the medical device depend on essential performance?	NO	NO

2.2 Hazard determination

2.2.1 Information Sources

The following information can be used to make a list of potential hazards:

Existing risk analysis reports for similar products;

Surveys of product developers;

Expert judgment;

Analysis of FDA medical device reports;

Research has been done to reduce the risks of similar products, and it is often assumed that the hazard exists;

Field data from similar products already in use, as well as service reports, complaints, and accident records.

2.2.2 Hazard determination checklist

Use ISO 14971 to determine the potential hazards to analyze the potential hazards of the product.

Energy hazard

	Cause	Marking
Electric energy	NO	
Heat energy	NO	
Mechanical force	NO	
Ionizing radiation	NO	
Non-ionizing radiation	NO	
Electromagnetic field	NO	
Moving parts	NO	
Hanging weight	NO	
Patient support failure	NO	
Pressure (vessel rupture)	NO	

Sound pressure	NO	
Vibration	NO	
Magnetic field	NO	

Biological hazard

	Cause	Marking
Biological pollution	Microorganism pollution	
Biological incompatibility	NO	
Incorrect input	NO	
Incorrect formula	NO	
Toxicity	NO	
Infection	NO	
Pyrogenic	NO	
Failure to maintain hygienic safety	NO	
Material degradation	NO	

Environmental hazard

	Cause	Marking
Electromagnetic interference	NO	
Improper supply of energy or refrigerant	NO	
Limitation of cooling	NO	
Possibility to operate outside specified environmental conditions	NO	
Incompatibility with other devices	NO	
Accidental mechanical damage	NO	

Contamination due to waste and equipment disposal	The product is not destroyed in time after use	

Hazards related to device use

	Cause	Marking
Inappropriate label	Misuse of incorrect information on the label; Too little information on the label causes misuse	
Inappropriate operating instructions	Difficult to understand the contents of the manual	
Inappropriate attachment specifications	NO	
Overly complicated operating instructions	NO	
No operating instructions	NO	
Use by untrained personnel	NO	
Foreseeable misuse in a reasonable manner	NO	
Inadequate warning of side effects	NO	
Inadequate warning of re-use of disposable medical devices	NO	
Incorrect measurements and other metrological issues	NO	
	Wrong operation	

Incorrect measurement		
Incorrect data transmission	NO	
Result error display	NO	
Incompatibility with consumables / accessories / other devices	NO	

Hazards due to functional failure, maintenance and aging

	Cause	Marking
Performance characteristics not suitable for the intended use	Product is expired	
Missing or inappropriate maintenance practices	NO	
Improper maintenance	NO	
Lack of specifications to end device life	NO	
Make the instrument complete	Damaged packaging	
Improper packaging	Unsuitable packaging materials	
Improper reuse	Reuse of disposable products	

2.2.3 Related potential hazards

The risk management team's determination of the relevant potential hazards is as follows:

Table 4 Hazard Identification

Hazard	No.	Foreseeable event	Possible damage
	H1	Unclear product	The product does not work correctly

Information hazard		packaging identification	
	H2	The description of the manual is not clear and understandable or the information is incomplete	The product does not work correctly
Use hazards and malfunctions	H3	Storage temperature exceeds 2 ℃ ~ 30 ℃	Product failure, inaccurate test results, affecting disease diagnosis
	H4	Beyond product life	Product failure, inaccurate test results, affecting disease diagnosis
	H5	Testing operations are not performed in accordance with operating requirements	Inaccurate test results affect disease diagnosis
	H6	Product reuse	Disposable products, inaccurate re-use results, affecting disease diagnosis
	H7	Product performance does not meet standards	The product is used unexpectedly and the test results are not accurate
	H8	Damaged packaging	Cause product failure
	H9	Product is broken	Cause product failure
	H10	The product is not destroyed in time after use	Environmental pollution
	H11	Unsuitable packaging materials	Light-transmitting materials cause product lighting failure
Chemical hazard	H12	Buffer splash	Buffer splashed into the body during use, causing damage
	H13	Materials and packaging materials are toxic	Cause poisoning

3 Risk assessment

3.1 Risk acceptance criteria

Table 5 Risk criterion

Common terms	Code	Possible description
Negligible	S1	Inconvenience or temporary discomfort
Minor	S2	Results in temporary injury or impairment not requiring Professional medical intervention
Serious	S3	Results in injury or impairment requiring professional medical intervention
Critical	S4	Results in permanent impairment or life-threatening injury
Catastrophic	S5	Results in patient death

3.2 Probability of damage

Table 6 Risk level

Common terms	Code	Examples of probability range
Improbable	P1	$<10^{-6}$
Remote	P2	$10^{-5}\sim10^{-6}$
Occasional	P3	$10^{-4}\sim10^{-5}$
Probable	P4	$10^{-3}\sim10^{-4}$
Frequent	P5	$\geqq10^{-3}$

3.3 Risk assessment criteria

Table 7 Risk assessment criteria

		S1	S2	S3	S4	S5
		Negligible	Minor	Serious	Critical	Catastrophic
Frequent	P5					
Probable	P4					

Occasional	P3					
Remote	P2					
Improbable	P1					

Description：

Acceptable risk；

Reasonably feasible risk reduction；

Unacceptable risk.

3.4Risk judgment

According to the risk management process, the hazards that have been subjected to risk analysis are classified according to Table 5, and the possible damages and preliminary control measures are analyzed.

Table 8 Risk judgment table

Hazard Type	No.	Foreseeable event	Possible damage	Preliminary control measures
Information hazard	H1	Unclear product packaging identification	The product does not work correctly	Strict packaging product packaging printing quality according to raw material procurement standards
	H2	The description of the manual is not clear and understandable or the information is incomplete	The product does not work correctly	Product manuals are compiled to be easy to understand and comprehensive
Use hazards and malfunctions	H3	Storage temperature exceeds 2 ℃ ~	Product failure, inaccurate test results, affecting	Indicate the storage conditions on the label and instructions.

		30 ℃	disease diagnosis	
	H4	Beyond product life	Product failure, inaccurate test results, affecting disease diagnosis	Indicate the shelf life on the label and instructions.
	H5	Testing operations are not performed in accordance with operating requirements	Inaccurate test results affect disease diagnosis	Warning operation requirements on labels and instructions
	H6	Product reuse	Disposable products, inaccurate re-use results, affecting disease diagnosis	Warn products on labels and instructions for single use
	H7	Product performance does not meet standards	The product is used unexpectedly and the test results are not accurate	Do factory inspection
	H8	Damaged packaging	Cause product failure	Do not use after the inner packaging is broken in the instructions
	H9	Product is broken	Cause product failure	Do not use the product if it is damaged in the instructions

	H10	The product is not destroyed in time after use	Environmental pollution	Explain how to dispose of waste in the instructions.
	H11	Unsuitable packaging materials	Light-transmitting materials cause product lighting failure	Purchasing materials in accordance with raw material procurement standards
Chemical hazard	H12	Buffer splash	Buffer splashed into the body during use, causing damage	Notes on buffer use in the instructions.
	H13	Materials and packaging materials are toxic	Cause poisoning	Purchasing materials in accordance with raw material procurement standards

3.5 Risk occurrence analysis

Analyze the probability of occurrence of hazards and hazardous situations and the probability of damage caused by risk analysis.

Table 9 Risk Probability Assessment Form

No.	Foreseeable event	Probability of causing damage
H1	Unclear product packaging identification	P3
H2	The description of the manual is not clear and understandable or the information is incomplete	P2
H3	Product reuse storage temperature exceeds 2 ℃ ~ 30 ℃	P2
H4	Beyond product life	P3
H5	Testing operations are not performed in	P3

	accordance with operating requirements	
H6	Product reuse	P3
H7	Product performance does not meet standards	P1
H8	Damaged packaging	P2
H9	Product is broken	P3
H10	The product is not destroyed in time after use	P3
H11	Unsuitable packaging materials	P2
H12	Buffer splash	P1
H13	Materials and packaging materials are toxic	P1

3.3 Level of risk damage

Analyze and assign values to the possible occurrence of the hazard and the severity of the damage determined by the risk analysis.

Table 10 Risk Damage Assessment Form

	Foreseeable event	Probability of causing damage
H1	Unclear product packaging identification	S1
H2	The description of the manual is not clear and understandable or the information is incomplete	S1
H3	Product reuse storage temperature exceeds 2 ℃ ~ 30 ℃	S1
H4	Beyond product life	S2
H5	Testing operations are not performed in accordance with operating requirements	S1
H6	Product reuse	S2
H7	Product performance does not meet standards	S2
H8	Damaged packaging	S1
H9	Product is broken	S2
H10	The product is not destroyed in time after use	S2
H11	Unsuitable packaging materials	S2

H12	Buffer splash	S3
H13	Materials and packaging materials are toxic	S3

3.4 Acceptable risk judgment

Table 11 Risk acceptability judgement

		S1	S2	S3	S4	S5
		Negligible	**Minor**	**Serious**	**Critical**	**Catastrophic**
Frequent	**P5**					
Probable	**P4**					
Occasional	**P3**	**H1、H5**	**H6、H9、H10**			
Remote	**P2**	**H2、H3、H8**	**H4、H11**			
Improbable	**P1**		**H7**	**H11、H13**		

Unacceptable

Research to further reduce risk

Acceptable

4 Risk control

4. Analysis of risk control plan

According to the requirements of the risk management plan, identify risk control measures from the following aspects:

a. Use design methods to achieve inherent security.

This includes eliminating specific hazards; reducing the probability of damage occurring; reducing the severity of the damage.

b. Protective measures of the medical device itself or during the manufacturing process.

c. Safety information.

Warnings, instructions for use are given in the documentation accompanying the product; restrictions on the use of medical devices or restrictions on the use of territory.

4.2 Risk control measures

After analysis, preliminary risk control measures were taken for the above judgment of unacceptable risks and reasonable reduction of risks.

Table 12 Risk control measures table

	Foreseeable event	Preliminary control measures
H1	Unclear product packaging identification	Strict packaging product packaging printing quality according to raw material procurement standards
H2	The description of the manual is not clear and understandable or the information is incomplete	Product manuals are compiled to be easy to understand and comprehensive
H3	Storage temperature exceeds 2 ℃ ~ 30 ℃	Indicate the storage conditions on the label and instructions.
H4	Beyond product life	Indicate the shelf life on the label and instructions.
H5	Testing operations are not performed in accordance with operating requirements	Warning operation requirements on labels and instructions
H6	Product reuse	Warn products on labels and instructions for single use
H7	Product performance does not meet standards	Do factory inspection
H8		Do not use after the inner

	Damaged packaging	packaging is broken in the instructions
H9	Product is broken	Do not use the product if it is damaged in the instructions
H10	The product is not destroyed in time after use	Explain how to dispose of waste in the instructions.
H11	Unsuitable packaging materials	Purchasing materials in accordance with raw material procurement standards
H12	Buffer splash	Notes on buffer use in the instructions.
H13	Materials and packaging materials are toxic	Purchasing materials in accordance with raw material procurement standards

4.3 Verification of the effectiveness of risk control measures

Table 13 Validation Effectiveness of risk control measures

No.	Risks before taking measures			Risks after taking measures			Whether new risks arise	Validation results
	Probability	Severity	Risk level	Probability	Severity	Risk level		
H1	P3	S1	Research to reduce risk	P2	S1	Acceptable	NO	Acceptable
H2	P2	S1	Acceptable	P2	S1	Acceptable	NO	Acceptable

H3	P2	S1	Acceptable	P1	S1	Acceptable	NO	Acceptable
H4	P3	S2	Research to reduce risk	P2	S1	Acceptable	NO	Acceptable
H5	P3	S1	Research to reduce risk	P1	S1	Acceptable	NO	Acceptable
H6	P3	S2	Research to reduce risk	P2	S1	Acceptable	NO	Acceptable
H7	P1	S2	Acceptable	P1	S1	Acceptable	NO	Acceptable
H8	P2	S1	Acceptable	P2	S1	Acceptable	NO	Acceptable
H9	P3	S2	Research to reduce risk	P2	S1	Acceptable	NO	Acceptable
H10	P3	S2	Research to reduce risk	P2	S1	Acceptable	NO	Acceptable
H11	P2	S2	Research to reduce risk	P1	S1	Acceptable	NO	Acceptable
H12	P1	S3	Research to reduce risk	P1	S2	Acceptable	NO	Acceptable
H13	P1	S3	Research to reduce	P1	S2	Acceptable	NO	Acceptable

			risk					

5 Residual risk assessment

After all risk control measures have been implemented and verified, each department considers whether all the comprehensive residual risks caused by the product are acceptable. If the decision is unacceptable, each department collects and reviews relevant information in order to determine whether the benefits exceed the residual risk. If the return exceeds the residual risk, the residual risk is acceptable.

5.1 Residual risk analysis

After all risk control measures, there is no longer any risk with an unacceptable level of risk and reasonable improvement. At the same time, it can be seen from the above analysis and verification that no new risks have been brought about after the implementation of all risk control measures, and the total comprehensive residual risk of the product may have the following:

a. The operation process is not accurate.

b. Discomfort of product storage environment.

5.2 Comprehensive residual risk analysis and assessment

The review team carried out a comprehensive assessment of the residual risks, taking into account the effects of all the individual residual risks.

6 Risk / benefit analysis

According to the results of risk control, it can be seen that there are no unacceptable risk items after the risk control measures are currently expected and known risks. The risk items with a risk level that is reasonably feasible have passed the remaining risks of the review team. Analysis, all residual risks are acceptable. Therefore, no risk / benefit analysis is required.

7 Assess secondary risks arising from risk control measures

According to the risk assessment generated by the risk control measures according to the "Table 11 Risk Control Measures Verification Effect", the control

measures will not cause new hazards, and the risks generated by all risk control measures have been considered and controlled.

8 Information about production and post-production

In order to obtain the production and post-production information of the product, the company compiled the "Quality Information Feedback Control Procedure". The review team evaluated the adaptability and effectiveness of the production and post-production information acquisition methods in the "Quality Information Feedback Control Procedure" It is concluded that the method is appropriate and effective. The production and post-production information acquisition can be obtained in accordance with the requirements of relevant procedures. The person responsible for project risk management manages the obtained production and post-production information.

9 Risk management review

9.1Risk management review input

9.1.1 Risk acceptance criteria

Accepted Criteria for Risk Management-see Table 4.

9.1.2 Risk Management Document

Risk management plan-see 1.5

Security characteristics analysis table-see Table 5

Risk assessment, implementation and verification of risk control measures-see Section 4

Evaluation of residual risk- see Section 5

9.1.3Risk assessment criteria

The risk assessment is performed in accordance with 《BS EN ISO 14971-2012 Medical devices — Application of risk management to medical devices (ISO 14971: 2007, Corrected version 2007-10-01)》

9.2 Completion of risk management plan

The review team checked the complete situation of the risk management plan one by one. By examining the relevant risk management documents, it was considered

that the risk management of SARS-CoV-2 IgG/IgM Rapid Test Device products was basically implemented.

9.3 Acceptable review of comprehensive residual risk

The review team conducts a comprehensive analysis of all remaining risks, and considers the effect of all individual residual risks. The review team believes that the comprehensive residual risk of the product is acceptable.

9.3.1 Are there conflicting requirements for risk control of individual risks?

Conclusion: No contradictions were found in existing risk control.

9.3.2 Review of warnings

Conclusion: The warning notice of the product is clear and meets the specifications.

9.3.3 Review of instructions

Conclusion: The instruction manual complies with the requirements of Annex IB 8, EN ISO 18113-4: 2011, EN ISO 18113-5: 2011. The product safety description is clear and understandable, and it is easy for users to read.

9.3.4 Review team conclusions

Conclusion: The systematic analysis review team believes that the remaining risks are acceptable.

9.4 Reviewed risk management documents

Save the review document.

10 Risk management review conclusions

Based on the above analysis and analysis of the SARS-CoV-2 IgG/IgM Rapid Test Device, according to 《BS EN ISO 14971-2012 Medical devices — Application of risk management to medical devices (ISO 14971: 2007, Corrected version 2007- 10-01)》 analytical program to conduct a risk assessment of this product. Although some risks are within acceptable limits, under the guidance of continuous improvement and excellence, the risk has been further reduced. Corresponding countermeasures and preventive measures have been taken to greatly improve product quality and ensure product safety and effectiveness.

For all identified residual risks, it is acceptable to use warning statements in the product instruction manual and packaging for the hazards in use. These risks can be

avoided during the medical process. Make the product can meet the medical requirements well during use.

Through various preventive measures formulated, we have effectively controlled the incoming inspection, manufacturing, process inspection, and final inspection in management, improving reliability and further reducing the probability of risk occurrence.

The product is completely acceptable to the remaining risks associated with the identified hazard under the intended application field and use case, and it is a universally usable, safe and effective product.