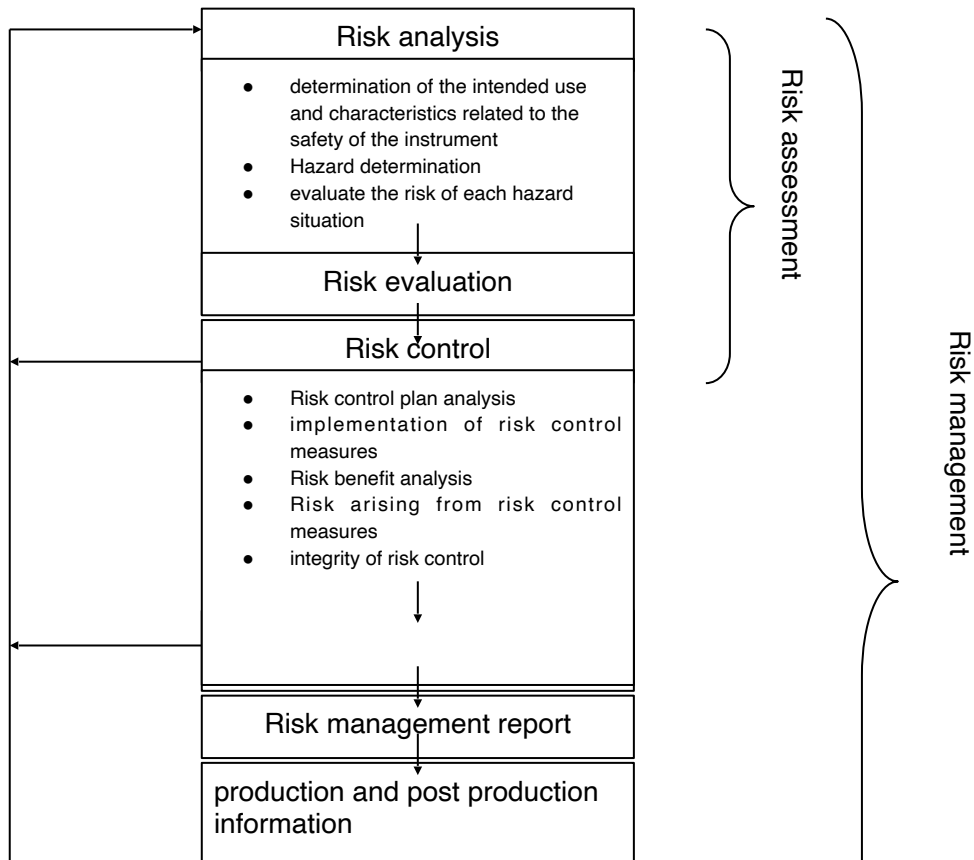


## 1、Preface

Acupuncture needles, as a medical device for the treatment of human diseases, have a long history of manufacture and application. Like other medical devices, Acupuncture needle design and manufacturing process, there are certain risks, in order to improve the safety of acupuncture needle, as much as possible without risk may receive damage, in accordance with the requirements of EN ISO 14971:2012 "—" medical risk management standards, specific combination of acupuncture needle products, we use the failure modes and effects analysis "(FMEA) techniques of acupuncture needle design and manufacturing process of risk analysis.

## 2、program flow diagram of risk analysis (Figure 1)

Figure1 : Sketch map of risk management process



## 3、Results of risk analysis of acupuncture needles

3.1 describe and identify the quality characteristics of acupuncture needles. See table 1.

3.2 identification of potential dangers of acupuncture needles. See table 2.

3.3 risk assessment of each risk. See table 3 and 4.

3.4 acceptability of risk.

Based on the identification of potentially dangerous and acupuncture needle for each kind of risk assessment, the effect of the potential failure severity, the potential failure causes the incidence and the current design (process control) detection of three factors to calculate the risk value of order "(R.P.N., 1-1000) to measure up to 24, this value is relatively low, means that the risk of various potential risk is very small, is the risk acceptable.

## 4、Discussion on risk analysis of acupuncture needles

4.1 the function of acupuncture needle

Piercing the skin used in acupuncture treatment.

4.2 technical standards for the implementation of acupuncture needles

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Acupuncture needle standard: China national standard GB2024-1994 "acupuncture needle" as the basis for design and manufacture.

4.3 the defects of acupuncture needle bring dangerous risk

4.3.1 Acupuncture needle is mass-produced products, although manufacturers will strive to make the waste to reduce as much as possible, but in the mass production of individual acupuncture needle defects can hardly be avoided for example: broken needle, needle, and the needle handle out, according to the provisions of general inspection level I sampling, acceptable quality level (AQL) for 1.5, the sample 500, allowing 14 unqualified (about 3%).

4.3.2 of the acupuncture needle, caused the failure of the most serious defects are broken needle, needle and needle handle from the company to strengthen the incoming inspection, 100% from qualified suppliers procurement of stainless steel wire, steel wire and hardness; needle and needle disease from the main reason is the needle and the needle handle connection without clamping, firm connection is not enough, the company to strengthen the connection in the needle and the needle handle the check, should maintain appropriate strength, so that the needle handle needle clamp body, using the above measures can be broken needle, needle and needle handle from the risk to low.

4.4 Microbial contamination of acupuncture needles

According to the medical guidelines 92/42/EEC appendix IX classification standard, the acupuncture needle belongs to class II, we present the acupuncture needle belongs to the production of sterile medical devices. EO sterilization is carried out before the sale of the product, with a carrier rate of SAL=10<sup>-6</sup>. The risk is small and acceptable.

4.5 The production and application of acupuncture needles

The acupuncture needle company meets the requirements of GB2024-1994, in each hospital using the feeHLack information, so far there is no medical accident and customer complaints phenomenon, so that the company's products are mature and effective.

4.6 Design, process failure modes and impact analysis

Acupuncture needle structure is simple, production process is not too complex, we use FMEA skills, acupuncture needle design and process two aspects of risk analysis. On the basis of the identification of potential dangers of acupuncture needles, the..... What will happen output ideas, table two and table three lists the problems gradually for risk assessment, modeled on the effect of the potential failure severity, potential failure causes and incidence of the current design process of detection, calculated the risk of order value (R.P.N.) are relatively small, the risk has been identified all kinds of danger are acceptable.

5 Concluding remarks

We refer to the risk analysis procedure stipulated in ISO 14971 medical device risk analysis standard, and carry out the risk analysis of acupuncture needles. In the process of risk analysis, the potential danger of using FMEA technique, risk assessment and order calculated values (R.P.N.) were lower, better safety, the acupuncture needle users, the risk of potential dangers brought by acceptable.

6 Risk Analyst:

Order Numb	personnel	post	department	Responsibilities in risk management
1	俞瑞兴	Group leader	General manager	The project leader Who is fully responsible for the risk management process
2	俞素琼	member	Quality department	Deputy project leader, responsible for the implementation of the risk management process Estimate operator errors from the application point of view
3	王君君	member	Production department	The probability of hardware failure is estimated from a technical point of view Determine possible manufacturing defects from a technical point of view Determine possible problems from the point of view of equipment operation

Enclosure: : Abbreviations used

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Risk Evaluation

Severity (9 – very severe, 0 –not severe)

Occurrence (9 – often, 0 – never)

Detection

(9 – impossible to detect before risk occurs,

0 – will be certainly detected before risk occurs)

Risk Level = Severity × Occurrence × Detection 1-9: neglect able risk, no further actions; 9-24: moderat minimal risk, preventive action recommended; 25-48: moderate risk, preventive action required; >48: ri is usually not acceptable

Risk Reduction Measure

New hazard generated (no/ yes - if yes, then number of new hazard indicated)

Acceptable Level of Risk

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Description and identification of quality characteristics of acupuncture needles(Table 1)				
Order numemb	Characteristics that may affect security	Yes	No	Describe it, if necessary
1	What are the intended uses of medical devices?			A. a doctor with professional experience B. needs C. in a clean clinic where the patient needs acupuncture E. is not a professional doctor and cannot be used
	A. How can medical devices be used?	√		
	B. User's technical and training	√		
	C. In what environment is it used?	√		
	D. Who installs it and does the user affect use of the device?		√	
	E. Special requirements for persons with disabilities, the elderly and children, this particular requirement may include the use of equipment by others.	√		
2	Are medical devices intended for implantation?	√		A. when acupuncture is used B. non contact C. is invasive contact D. non implantation E. each contact time is general not more than 60 minutes.
	A. Surface contact	√		
	B. Intrusive contact	√		
	C. implantation	√		
	D. Contact period and frequency	√		
3	Are medical devices expected to be in contact with patients or other people?	√		Patients and doctor

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4	What materials or components are used in medical device? Or what materials or components are used in conjunction with medical devices or in contact with the product? <span style="float: right;">√</span>	Acupuncture needles are mainly made of stainless steel wires. The product is not used and contacted by any material or component.
5	Is there energy available to the patient or for the patient? <span style="float: right;">√</span>	
6	Is there a substance available to the patient extracted from the patient? <span style="float: right;">√</span>	
7	Are biological materials treated by medical devices and used for re-use? <span style="float: right;">√</span>	
8	Are medical devices provided in sterile form or are expected to be sterilized by users or controlled by other microbiological methods? <span style="float: right;">√</span>	Acupuncture needles are disposable products, and they are sterilized products.
9	Are medical devices expected to be routinely cleaned and sterilized by users? <span style="float: right;">√</span>	
10	Are medical devices expected to improve the patient's environment? <span style="float: right;">√</span>	
11	Is the measurement carried out? <span style="float: right;">√</span>	
12	Are medical instruments analyzed and handled? <span style="float: right;">√</span>	
13	Are medical devices expected to be used in conjunction with other instruments, medical or medical technology? <span style="float: right;">√</span>	

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Description and identification of the quality characteristics of acupuncture needles (continued from 1)					
Order number	Characteristics that may affect security	Yes	No	Describe it, if necessary	
14	Is it produced by an unexpected energy or substance?		√		
15	Are medical devices sensitive to the environment?	√		The acupuncture needle is mainly composed of stainless steel wire, stored temperature ≤ 40°C, humidity ≤ 80%, Non corrosive gas in the interior.	
16	Does medical equipment affect the environment?		√		
17	Are there any basic supplies or accessories related to medical equipment?		√		
18	Is it necessary to perform maintenance or calibration?		√		
19	Does the medical device include software?		√		

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20	Is there a storage life restriction for medical devices? <span style="float: right;">√</span>	The storage life of acupuncture needles is generally not longer than 5 years from the date of manufacture
21	Is there a delayed or long-term use effect? <span style="float: right;">√</span>	
22	What mechanical forces do medical devices bear? <span style="float: right;">√</span>	
23	What determines the life span of medical devices? <span style="float: right;">√</span>	In the course of storage, the packaging materials of acupuncture needles will gradually aging, the bacteria resistance is poor, and whether or not bacteria is the most important factor to determine the life span of the product.
24	Are medical devices expected to be used only once? <span style="float: right;">√</span>	Acupuncture needles clearly defined for disposable use.
25	Do medical devices need safe exit, use, or disposal? <span style="float: right;">√</span>	
26	Does the installation or use of medical devices require specialized training or specialized skills? <span style="float: right;">√</span>	
27	How is security usage information provided? <span style="float: right;">√</span>	
28	Is there a need to establish or introduce new production processes? <span style="float: right;">√</span>	
29	The success of medical devices depends critically on human factors, such as user interfaces <span style="float: right;">√</span>	
30	Does the medical device use an alarm system? <span style="float: right;">√</span>	
31	In what cases can medical devices be intentionally misused? <span style="float: right;">√</span>	
32	Are medical devices vital to patient care? <span style="float: right;">√</span>	
33	Are medical devices expected to be mobile/portable? <span style="float: right;">√</span>	
34	The use of medical devices depends on their fundamental performance <span style="float: right;">√</span>	

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Identification of potentially dangerous acupuncture needles (table 2)

Order number	Possible danger	yes	No	Normal condition	Failure condition	If yes, possible danger description
1	Energy risk		√			
	A. electromagnetic energy		√			
	B. radiation energy		√			
	C. thermal energy		√			
	D. mechanical energy		√			

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2	Biological hazard					
	A. biological load		√			
	B. biological pollution		√			
	C. biocompatibility	√			√	The needle is made of 0Cr19Ni9 or other austenitic stainless steel wire, as specified by ISO7153-1, and has biocompatibility
	D. incorrect output		√			
	E. incorrect recipe		√			
	F. chemical toxicity		√			
	G. cross infection	√			√	Cross infection may occur when the same needle is used by different users.
3	Environmental risk					
	A. electromagnetic interference		√			
	B. inadequate coolant supply		√			
	C. inadequate coolant supply		√			
	D. exceeds the possibility of operating under specified environmental conditions		√			
	E. physical (e.g., heat, pressure, time)		√			
	F. Chemistry (corrosion, degradation)		√			
4	Hazards associated with the use of machinery					
	A. inappropriate labels	√			√	Use during the validity of the product.
	B. inappropriate operating instructions	√			√	It should be used by professional doctors and strictly prohibited by non-professional doctors.
	C. inappropriate attachment specifications		√			
	D. too complex operating instructions		√			
	E. invalid or separated operation instructions		√			
	F. side effects are not adequately warned		√			

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Identification of potentially dangerous acupuncture needles (continued table 2)						
Order numbe	Possible danger	Yes	No	Normal conditio	Failure conditio	If yes, possible danger description
4	G. is used by unskilled or untrained personnel	√			√	Prohibit the use of non professional doctors
	H. human error	√			√	Acupuncture needles; repeated use; leading to cro infection.
	I. incorrect measurements and other meteorological aspects		√			
	J. incorrect diagnosis		√			
	K. error data transfer		√			
	Error representation of L. results		√			
5	Risk of functional failure, maintenance, and aging					
	A. is expected to use inappropriate performance characteristics	√			√	Acupuncture needles can be stored in an unsuitable environment and may cause functional failure.
	B. lack of maintenance instructions		√			
	C. incorrect maintenance	√			√	Acupuncture needles; repeated use; leading to cro infection.
	D. lacks proper decisions about the end of mechanical life		√			
	E. loses mechanical integrity		√			
	F. improper packing (contamination and / or damage of equipment)	√			√	Contamination or damage caused by breakage or opening of an acupuncture package.
6	Hazards arising from manufacturing processes					Failure to produce in specified products and specifications.
	A. risk in the contract review phase	√			√	The mixing of hair, wool and other sundries leads to risks in use.
	B. inadequate manufacturing process change control.	√			√	Contamination or damage caused by breakage or opening of an acupuncture package.

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Design failure modes and failure effects analysis (DFMEA) (table 4)

project	Potential failure modes	Potential failure impact	Severity	Potential failure cause / mechanism	Occurrence	Current design control	Degree of difficulty	Risk subordinal	Recommended measures	Measure result				
										Take steps	Severity	Occurrence	Degree of difficulty	risk Order number
2C Biocompatibility	failure mode: In the process of purchasing raw materials, the material is unstable	By not GB/T4091 stainless steel wire or may lead to the failure of biocompatibility	6	Raw materials purchased by unqualified suppliers.	1	Check and test the stainless steel wire imported into each and obtain the warranty and material report at the same time.	3	18	Not necessary					
2G cross infection	The same acupuncture needle is used by different users.	Cross infection among different users.	6	The user does not use the product in accordance with packaging instructions or instructions.	1	The packaging, identification and instruction of acupuncture needles clearly re-disposable product	1	6	Not necessary					
4A Improper label	Use over validity	Cause bacterial infection	6	The user has used it with validity period marked by the package	1	The packing material of acupuncture needles indicate the validity period	1	6	Not necessary					
4B Improper appropriate	Non professional acupuncture use	non special acupuncture lead to medical malpractice	8	The user has used the warning language marked by the package	1	The product packaging label indicates professional acupuncture is allowed to use	1	8	Not necessary					

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Design failure modes and failure effects analysis (DFMEA) (table 4)

project	Potential failure modes	Potential failure impact	Severity	Potential failure cause / mechanism	Occurrence	Current design control	Degree of difficulty	Risk subordinal	Recommended measures	Measure result				
										Take steps	Severity	Occurrence	Degree of difficulty	risk Order number
4F.Used by unskilled untrained personnel	Non professional acupuncture use	The use of non special acupuncture can lead to medical malpractice	8	The user has not used the warning language marked by the package	1	The product packaging label indicates professional acupuncture is allowed to use	1	8	Not necessary					



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4G.mistake people	Damaged or exceeding validity of packing.	The small of the needle will cause bacterial infection	8	Improper transportation, handling, storage	2	The packing mark of indicates that the small is damaged or beyond validity period and is allowed to use	1	16	No necessary					
5A. Improper character	Did not choose right acupuncture point and the corresponding specifications product	When the correct acupuncture points corresponding specifications are not chosen, the treatment invalid.	8	Not proficient in the use of acupuncture needles	2	Instructions for use of acupuncture indicate the method use.	1	24	No necessary					

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Design failure modes and failure effects analysis (DFMEA) (table 4)

project	Potential failure modes	Potential failure impact	Severity	Potential failure cause / mechanism	Occurrence	Current design control	Degree of difficulty	Risk sub ordinal	Recommended measures	Measure result				
										Take steps	Severity	Occurrence	Degree of difficulty	risk Order number
5C Incomplete maintenance	Premature failure of product	Cause bacterial infection of acupuncture needles	5	The product stored in a environment where temperature and humidity are too high	3	Instructions for use of the package clearly indicate that needles should be stored in cool and dry place	1	15	Not necessary					
5F. Improper packing	Packaging failure of acupuncture needles	Bacterial infection caused by package breakage of acupuncture needles	8	Packing and unloading during loading are not careful and lead to packaging damage.	1	When packaging inspection personnel required to check quality of packaging and packaging verification.	2	16	Not necessary					
6A Risk in the contract review phase	Failure of product in specified products and specifications.	Delivery not delivered according to specified products and specifications	8	The contract review time carelessness leads to the contract products and specifications out of contract	1	In the contract review strengthen the contract terms, products, specifications and assessment, and according to contract requirements for production.	1	8	Not necessary					

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Design failure modes and failure effects analysis (DFMEA) (table 4)

project	Potential failure modes	Potential failure impact	Severity	Potential failure cause / mechanism	Occurrence	Current design control	Degree of difficulty	Risk sub ordinal	Recommended measure	Measure result				
										Take steps	Severity	Occurrence	Degree of difficulty	risk Order number
6B Inadequate manufacturing process change control	Hair, wool and other sundries mixed into the use of risk	Risk in use	8	The production process is of control	1	To strengthen the inspection of finished product inspection procedures; to prevent the inclusion of hair, wool and other sundries into the product, make sure that each product has been inspected, Quality release.	1	8	Not necessary					

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Process failure modes and failure effects analysis (PFMEA) (table 4)

project	Potential failure modes	Potential failure impact	Severity	Potential failure cause / mechanism	Occurrence	Current design control	Degree of difficulty	Risk sub ordinal	Recommended measure	Measure result				
										Take steps	Severity	Occurrence	Degree of difficulty	risk Order number

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Purchas	The hardn of the nee is too larg the surfac the needle scratched cracked, causing th dangerous section	Broken needle	8	Defects in incoming inspection	2	(1) when buying, th sampling of the bill be representative, a hardness value sho rejected. (2) inspec surface of the billet 10X magnifying gl with 10X magnifyi when grinding and and check with the microscope when t process is checked accepted,	1	16	Not ness ry					
Needle grinding and polishin process	Acupunct needle tip damage	Damage the skin when pulling	7	Operator' work erro process inspection not prope	1	Strengthen the insp the needle grinding polishing process, t inspection before p and eliminate the n with burrs or barb.	2	14	Not ness ry					
Knock o the cutt process	The connection between t needle and needle han is not firm enough	The nee body is separate from the handle o the nee	6	Operator' work erro process inspection not prope	2	To strengthen the n body cutting proces on, only to meet the requirements to use	1	12	Not ness ry					