NAME & FUNCTION	DATE	VISA
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❖ Documentary links:

1) Risk Management Plan
2) Safety characteristic problem list and possible hazard analysis table;
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❖ Modification History:

No. Version	Date	Reason for modification

1. Objective:

The purpose of this report is to validate the medical cooling gel sheet.

2. Responsibilities:

The Quality & Regulatory Affairs department is responsible for writing and updating this validation report. And obtaining top management approval for the validation report.

3. Use requirement of the medical device:

Through the polymer hydrogel with sodium polyacrylate as the base material, a large amount of purified water is loaded into the polymer gel. The heat generated by the human body when it has a fever is taken away by absorbing heat through the evaporation of water, thereby achieving the effect of cooling down and reducing fever, which has a physical cooling effect.

4. Main service functions:

This product is used for physical fever reduction and cold compress therapy and is only used on intact skin on the body surface.

5. Risk analysis and results:

The review team conducted a comprehensive analysis of all residual risks, considering the combined effects of all individual residual risks. The review results show that the overall residual risk of the product is acceptable. The following are the specific evaluation aspects:

1) Are there conflicting requirements for risk control of individual risks?

Conclusion: No conflicting risk controls were found.

2) Review of warnings (including are there too many warnings?

Conclusion: The warning instructions are clear and in compliance with the regulations.

3) Review of instructions (including whether there are any contradictions or whether it is difficult to comply with).

Conclusion: The product manual complies with the requirements of laws and regulations and product-specific safety standards. The description of relevant product safety aspects is clear and easy to understand for users to read.

4) Compare with similar products.

Conclusion: After analyzing the above aspects, the risk management review team unanimously evaluated that the comprehensive residual risk of this product is lower than that of similar products.

5) Conclusion of the review team.

Conclusion: After analyzing the above aspects, the risk management review team unanimously concluded that the overall residual risk of this product is acceptable.

Refer to the following documents:

"List of Safety Feature Issues and Possible Hazards" (see Annex 1), which is a record of the analysis of the product's intended use, safety-related characteristics and possible hazards during product design and development.

Initial Hazard Identification and Initial Risk Control Measures (see Annex 2), which is a record of the reasonably foreseeable sequence of hazardous events under normal and fault conditions and the hazardous situations, possible damages and initial control measures that may be caused.

"Risk Assessment, Risk Control Measures and Residual Risk Assessment Record Form" (see Annex 3), which is the implementation and verification of risk assessment and risk control measures.

6. Conclusion

The risk management review team, after reviewing the products produced and the risk management process by checking the risk management documents, believes that:

- The risk management plan has been appropriately implemented;
- The overall residual risk is acceptable;
- There are appropriate methods to obtain relevant production and post-production information;
- The total residual risk is within the acceptable range of the risk acceptability criteria and the benefits outweigh the risks.

Annex 1

List of safety feature issues and possible hazards. This list is based on the list of issues in Appendix C and hazard examples in Appendix E.1 of the **EN ISO 14971:2019** standard and supplements the unique safety issues of the relevant products.

Contents of the question	Characteristic judgment	Probable Harm
C.2.1 What is the intended use of the medical device and how is the medical device used?	See Product description	None
C.2.2 Is the medical device intended to implant?	No	None
C.2.3 Is the medical device intended to come into contact with the patient or other person?	Yes, cooling patch in contact with patients.	Biological hazard
C.2.4 What materials or components are used in, or in conjunction with, or in contact with medical devices?	Yes, the use of non-woven fabrics and polypropylene films in medical devices	Biological hazard
C.2.5 Is there energy given to or taken from the patient?	No	None
C.2.6 Was any substance provided to or extracted from the patient?	No	None
C.2.7 Does the medical device process biological material for subsequent reuse, infusion/blood, or transplantation?	No	None
C.2.8 Is the medical device provided in sterile form or intended to be sterilized by the user, or with other applicable microbiological control protocols?	No	Biological hazard
C.2.9 Is the medical device expected to be routinely cleaned and disinfected by the user?	No	None
C.2.10 Is the medical device expected to improve the patient's environment?	No	None
C.2.11Whether to Take a measurement?	No	None
C.2.12 Is the medical device analyzed?	No	None
C.2.13 Is the medical device intended to be used in combination with other medical devices, medicines or other medical technologies?	No	None
C.2.14 Is there an unwanted output of energy or matter?	No	None
C.2.15 Are medical devices susceptible to environmental influences?	No	None
C.2.16 Do medical devices affect the environment?	No	None
C.2.17 Does the medical device have basic consumables or accessories?	No	None
C.2.18 Does it require maintenance and calibration?	No	None

C.2.19 Does the medical device contain software?	No	None
C.2.20 Is there a storage life limit for medical devices?	Yes, the shelf life is three years	Use hazard
C.2.21 Are there delayed or long-term use effects?	No	None
C.2.22 What mechanical forces do medical devices bear?	No	None
C.2.23 What determines the life of a medical device?	Moisture and stickiness in gels	Hazards of use
C.2.24 Is the medical device intended for one-time use?	YES	None
C.2.25 Does the medical device need to be safely removed from service or disposed of?	NO	None
C.2.26 Does the installation or use of medical devices require specialized training or specialized skills?	N0	None
C.2.27 How Do I Provide Safe Use Information?	Safe use information is detailed in the product manual	Information Hazards
C.2.28 Is it necessary to establish or introduce new manufacturing processes?	NO	None
C.2.29 Successful use of medical devices. Is it critically dependent on human factors, e.g. user interface?	NO	None
C.2.29.1 Are User interface design features likely to cause usage errors?	NO	None
C.2.29.2 Is the medical device used in an environment where it is used incorrectly due to distraction?	NO	None
C.2.29.3 Does the medical device have connecting parts or accessories?	NO	None
C.2.29.4 Does the medical device have a control interface?	NO	None
C.2.29.5 Does the Medical Device Display Information?	NO	None
C.2.29.6 Are medical devices Controlled by menus?	NO	None
C.2.29.7 Is the medical device used by a person with special needs?	NO	None
C.2.29.8 Can the User Interface be Used to initiate User actions?	NO	None
C.2.30 Does the medical device use an alarm system?	NO	None
C.2.31 In what ways may a medical device be intentionally misused?	Ingestion	Gastrointestinal hazards
C.2.32 Does the medical device hold critical data for patient care?	NO	None
C.2.33 Is the medical device intended to be mobile or portable?	Yes, medical fever strips are portable	Hazard of use
C.2.34 Does the use of medical devices depend on basic performance?	NO	None

Annex 2

Initial hazard analysis (PHA), including the foreseeable sequence of events, the hazard situation and possible damage, and the initial control measures taken.

Serial Number	Predictable events and sequence of events	Initial risk control measures
H1	The product has not been biologically evaluated	The product has been biologically evaluated
H2	The selection of non-woven fabric and anti-adhesive layer has not been evaluated by biology, the use of bioincompatible materials	Purchasing Control
H3	Microbe exceeding the standard	1. Enhanced process control 2. Strengthen inspection efforts
H4	Products that have passed their sell-by date are still in use	The instructions state the use-by date and information about the type used within the use-by date
H5	The moisture loss in the product seriously does not meet the requirements of the product, and the viscous dispersion is still in use	1. Design and development to strengthen the viscosity of the product research 2. Control the sealing of product packaging
H6	The safety information on the product manual is incomplete	Instructions in the instruction manual
H7	Use the product directly without cleaning and disinfecting the newly injured wound	Instructions in the instruction manual

Annex 3

1. Risk assessment, risk control measures and residual risk assessment record form.

Serial Number	Risk assessment before taking action			Post-action risk assessment			Whether new risks arise	Verify results
	Probability	Severity	Risk Level	Probability	Severity	Risk Level	Yes/No	Yes/invalid
H1	S2	P1	A	S2	P1	A	No	invalid
H2	S2	P3	R	S2	P1	A	No	invalid
H3	S2	P3	R	S2	P1	A	No	invalid
H4	S2	P2	A	S2	P1	A	No	invalid
H5	S1	P3	A	S1	P2	A	No	invalid
H6	S2	P1	A	S2	P1	A	No	invalid
H6	S2	P1	A	S2	P1	A	No	invalid

2. In the process of design and development, the use of FMEA, PFMEA, for the failure mode related to product safety, according to the risk management process, risk analysis, risk evaluation and risk control.

The process flow chart is as follows:
Procurement of raw materials → incoming inspection → qualified warehousing → preparation → kneading (▲) → coating (▲) → standing → Outsourcing → finished product testing → qualified warehousing.

Note: ▲ Key processes:

Process	Potential failure mode	Potential failure consequences	Severity degree	Grade	The cause and mechanism of potential failure	Occurrence frequency	Current design control	Results of measures			Risk identification
								Measures taken	Severity degree	Occurrence frequency	
Kneading coating	The colloid crosslinking degree of the product is not strong enough, and its	The cooling effect of the product is not good	P2	Key	There is an error in the order of adding materials, and the thickne	P2	Set up production process monitoring and first piece inspection	The production operation can be carried out only after the inspection is qualified,	S1	P2	H5

	weight and appearance are not up to standard.				ss of the coating setting is too small or too large.			and the staff will be trained in the GMP workshop regularly to strengthen the inspection.			
insourcing	The sealing of the included products is not good.	Loss of product performance	P2	Important	The package is not sealed, and the gel contains moisture loss.	P2	Design requirements, packaging requirements and corresponding inspection requirements	Formulate the corresponding process inspection rules and inspect them as required, verify and confirm the packaging equipment as required and maintain regularly according to the maintenance plan	S1	P1	H5