Jiangsu TaiMedical Technology Co., LTD

Technical Documentation of Tape

File NO.: TDNT-CE-Tape

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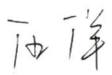
Wangyang Technical Manager		2022.8.6
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Zhuzhicai Vice General Manager		2022.8.6

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1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1 Device Description and Specification

1.1.1. Tape

The following variants of the medical device products intended to be made available on the market

Product Trade Name	Brands	Class
Tape((PaperPore、PE Tape、Nonwpore 、WaterProof、SilkPore、LightFix、Cross Tape、Foam tape 、ElastoPlus HM、kinesiology tape、cohesive bandage、LockerTape)	ZZ	I

1.1.2. Intended Use and Users

1.1.2.1 Intended Use

Mainly used in hospital trauma bandaging, dressing fixation, joint protection.

The product is roll-shaped, and the user can cut and use it according to the actual use position. The product does not have automatic functions;

1.1.2.2 Users

The intended users of the product are children and adults, infants and pregnant women, and should be used under the guidance of a doctor;

1.1.3. Precautions, Warnings and Contraindications

1.1.3.1Precautions and Warnings

Do not use the product after its expiry date or the product is contaminated.

1.1.3.2Contraindications

1.1.3.2.1 Use with caution in patients with a history of allergies to latex water;

1.1.3.2.1 The product should not be pasted directly on the wound when in use;

1.1.3.2.1 When used by pregnant women or children under18 months of age, customers should be advised to use it with caution or on the advice of a doctor;

1.1.4. Device Description

1.1.4.1. Device Description Including Variants and Accessories

Tape is composed of PE film、paper、Non-woven、cotton、Silk cloth、Foam……, acrylic glue and paper core tube. It is made by applying acrylic glue on PET film, drying and rewinding and slitting. The 3H brand sells products. According to different customer needs, the product contains different specifications. For specific specifications, see Appendix 1: "Product Specifications";

No accessories (except packaging) that came with the product when it was sold;

1.1.4.2. Mode of Action and Principles of Operation

This product is already widely used in the market. The product is coated with glue and has a self-adhesive effect. The base material of the product has a certain strength and is easy to tear. The elasticity of the base material itself and the professional application method can make the bandage have a certain degree of human body Bandage fixation.

The product can be used with other instruments for catheter fixation, etc .;

1.1.4.3. Key Functional Elements

1.1.4.3.1 Product Image

1.1.4.4. Explanation of Novel Features

The type of the device is well known and incorporates no novel features.

1.1.4.5. Composition

The product is composed of PE film and glue. Non-woven fabric accounts for about 60-70%, and glue accounts for about 30-40%;

The glue is Acrylic adhesive;

1.1.4.6. Raw Materials

The main raw materials of the product are non-woven fabric and glue;

Non-woven material is PE, glue is Acrylic adhesive;

product name	Material name	Supplier name
Tape	material	Nanjing Fushun Plastic Industry Co., Ltd. Nanjing Wanwo Paper Co., Ltd. Huzhou Changyin Textiles Co.,Ltd. Hubei Xiangyuan New Material Technology Inc. Jiangsu Shuangma Digital Technology Co., Ltd.
	acrylic glue	WeiFang Cofuller New Materials Co.,Ltd.

1.1.4.7. Specifications

1.1.4.7.1 Raw material specification information:

1.1.4.7.1.1 PE film

NO.	Test items	unit	Inspection standards	Testing method

1	Square weight	g/㎡	30-150	ZZNQ-MD02
2	width	cm	50-120	ZZNQ-MD03

1.1.4.7.1.2glue

NO.	Test items	unit	Inspection standards	Testing method
1	appearance	/	Colorless or light yellow transparent liquid, the material can't have a lot of bubbles.	ZZNQ-MD48
2	Solid content	/	45%±5%	ZZNQ-MD33
3	Inspection report	/	Need to provide qualified quality inspection report	ZZNQ-MD40

1.1.4.7.2 The materials used in the product are free of pharmaceutical and animal-derived substances, see the attached statement，

annex 2 " Declares that the product is free of substances of drug and animal origin ".

1.1.5. Medical Device Nomenclature

product name：Tape；

According to the UMDNS_code naming rules and product characteristics, the UMDNS_code of this product is:

UMDNS_code: 10032 Tapes, Adhesive

1.1.6. Device Identification and Basic Unique Device Identification

UDI-DI：NA

1.1.7. Intended Patient Population and Medical Conditions

1.1.7.1 The product is composed of PE film and glue. The base material of the product has a certain strength and is easy to tear in both directions. Professional application methods can make the bandage have a certain bandaging and fixing effect on the human body.

Product packaging contains boxes to ensure that the product will not be damaged and product protection;

1.1.7.2 The intended use of the product is children and adults, infants and pregnant women and pregnant women need to use under the guidance of a doctor;

1.1.7.3 Precautions and warnings:

1) Use with caution in patients with a skin allergy history;

2) It is forbidden to use the product on the wound;

3) Do not use the product after its expiration date or the product is contaminated;

4) Clean the skin with water or alcohol before use;

5) This product is a single-use product, please do not reuse it.

1.1.8. Additional Information Required in Specific Cases

Not applicable.

1.1.9. Risk Classification and Rationale for Qualification as a Medical Device

1.1.9.1. Risk Classification:

1.1.9.1.1 Products are classified as non-invasive passive medical device products for short-term use according to the classification rules in Appendix VIII, and the products are low-risk products;
1.1.9.1.2 According to the Medical Device Regulation REGULATION (EU) 2017/745 Appendix VIII Classification Rule Chapter 3 Rule 1, the product is classified as Class I;

RULE 1 –All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies. :	**VERDICT**
- Devices used to immobilize body parts and / or to apply force or compression on them.	I 类

1.1.9.2. Rationale for Classification as a Medical Device:

RULE 1 –All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies. :

- Devices used to immobilize body parts and / or to apply force or compression on them.

1.1.9.3. Rationale for Medical Device Qualification:

Following the definition of medical device given in §2 (1) of the MDR and in 3.11 of EN ISO 13485: 2016 and taking into account the intended use given above the product is classified as a medical device.

The device/ accessories is/are used for Medical fixed use.

1.1.9.4. EC- Declaration of Conformity

See annex3：EC - Declaration of Conformity（MDR）

1.2 Reference to Previous and Similar Generations of the Device

1.2.1. Previous Generations

This is the first generation of the devices marketed by HB， No change.

1.2.2. Similar Devices and Devices Produced by the Supplier

Similar devices are marketed for years by many manufacturers including, for example, 3M Transpore by 3M.
These products are consistent in structure and use, and are used for fixed use.

1.2.3. Similar Devices and Devices Produced by Competitors/ other Companies

Similar devices are marketed for years by many manufacturers including, for example, Transpore by 3M. These products are consistent in structure and use, and they all have self-adhesive effects and are used for fixed use.

1.2.4. Certificates and Registrations in the Union and Internal Markets

The medical devices of this technical file are sold in following counties.

- USA 3M Transpore

1.2.4.1. Country Registrations

Not applicable

1.2.4.2. Certificates of Free Sales (CFS)

Not applicable

1.2.4.3. U.S. Certificate of Foreign Government (CFG)

Certificate 3016837630.

2.INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

2.1 Labels and Instruction for Use

Product sales are generally sold in carton units (such as 12 rolls, 24 rolls, etc.). A single roll of product is protected by a packaging film, placed in a carton, and multiple cartons are placed in a shipping outer box. Product Manual;
Product artwork see annex4：Packing.

2.2 Packaging

Product sales are generally sold in carton units (such as 12 rolls, 24 rolls, etc.). A single roll of product is protected by a packaging film, placed in a carton, and multiple cartons are placed in a shipping outer box. Product Manual;

Packaging	**Material**
Primary	paper
Secondary	Box（paper）
Tertiary	Carton box（paper）
Accessory	Product Manual

2.3 Data Sheets for the Customer

Not applicable

2.4 Re-Sterilization and Re-Use of the Device

Not applicable

3.DESIGN AND MANUFACTURING INFORMATION

3.1 Compliance and Quality Agreement

Declaration of Responsibility

Jiangsu TaiMedical Technology Co., LTD. hereby declares that the product meets the relevant requirements of the Regulation (EU) 2017/745 (MDR). The information in this technical file is based on the information of the supplier and represents the current version of the original file. Changes need to be notified to the manufacturer, by the supplier as per Agreement of Compliance and are incorporated by the manufacturer. The technical documentation file is maintained for a minimum of 10 years after the manufacturing of the product.

The quality agreement (Agreement of Compliance) between the supplier and Jiangsu TaiMedical Technology Co., LTD. covers the exchange of information regarding significant changes, mutual responsibilities with regard to most market surveillance and audits, and access to documentation for the virtual manufacturer as well as the notified body retained by the virtual manufacturer. Equivalent devices of supplier and virtual manufacturer are listed. The quality agreement ensures compliance with the requirements of the Medical Device Regulations.

3.2 Design History

Not applicable

3.3 Specifications/ Acceptance Criteria

No medicinal substances, human blood derivates or other human derived substances, tissues of animal or human origin, software, or nanomaterials are incorporated in the device.

The specification: see annex 1： Product Specifications.

Annex5： Acceptance criteria

3.4 Legal Manufacturer Information

The device is manufactured for and on behalf of the Legal Manufacturer:

The manufacturer is Jiangsu TaiMedical Technology Co., LTD.

The manufacturer has established and maintains a Quality Management System which meets the requirements of directive 93/42/EEC (MDD), regulation (EU) 2017/745 (MDR) Annex II .

Name of Legal Manufacturer/ Name of EC Representative (EC REP)	Address of Legal Manufacturer	ISO Certificates	Notified Body

Jiangsu TaiMedical Technology Co., LTD	Building 1, 56 Youshan Road, Gaochun Economic Development Zone, Nanjing.	MDR: N/A（Class I medical devices）	

3.5 Manufacturing Site

The device is produced by the following supplier: Jiangsu TaiMedical Technology Co., LTD.

Name of Supplier with EC Rep：

Kingsmead Service B.V.

Zonnehof 36, 2632 BE, Nootdorp, Netherland

NL-AR-000002066

+31(0)646571005

office@kingsmead-service.com

We has established and maintained a Quality Management System which meets the requirements of regulation (EU) 2017/745 (MDR) Annex IX and EN ISO 13485:2016.

Name of Supplier/ Name of EC Representative (EC REP)	**Address of Supplier/ Production Site**	**ISO Certificates**	**Notified Body**
Jiangsu TaiMedical Technology Co., LTD	Building 1, 56 Youshan Road, Gaochun Economic Development Zone, Nanjing.	MDR: N/A（Class I medical devices）	

3.6 Manufacturing Information

3.6.1. Manufacturing Process

a. Product production is carried out in accordance with the documentation. The product production flow chart is implemented. Each production process has a process control plan. Process inspectors perform inspections in accordance with the requirements of the documents.

b. The product production environment is a conventional environment. It is cleaned daily to keep the workshop tidy and the equipment is inspected and maintained daily.

c. Product production is strictly implemented in accordance with the ISO13485 system, the production process is performed according to documents, process quality control requirements are formulated for each process, and inspectors are arranged for quality inspection at each process;

d. The product will be inspected by inspection personnel from the raw material entering the factory, the production process, and the completion of the product;

e. Production equipment will formulate equipment operation instructions;

f. When the product is in production, equipment parameters are verified for the key process-the coating process;

3.6.2. Sterilization Process

N/A.

3.6.3. Manufacturing Flow Chart

See Annex6：Manufacturing Flow Chart

4. General Safety and Performance Requirements

4.1General Safety and Performance Requirements Check List

See annex7：General Safety and Performance Requirements Check List.

4.2Transport Conditions

For the transport of the device,During the transportation of the product, avoid strong collision, strong fall, and scratching. The transportation vehicle can be a general van or container. It can be transported by air, sea or land, without other special requirements;
If there are special requirements, the labeling will be explained on the shipping carton;

4.3 Method of Disposal

Observe the applicable disposal regulations for your area.

4.4 Disposal of Main Device and Accessories

Observe the applicable disposal regulations for your area.

4.5 Disposal of the Packaging Material

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and processing system. This way, you will contribute to the recycling of raw materials and avoidance of waste.

5. Benefit-Risk Analysis and Risk Management

Product risk analysis according to EN ISO 14971, product risk is acceptable,

See annex 8：Tape of Risk Management Report.docx

6.Product Verification and Validation summary

6.1 Pre-clinical Data

6.1.1. Performance Testing and Safety

Performance was tested according to Company standards and customer needs, The test report is shown in Annex 9: Product Test Report；

Because this product does not currently have an EU reference standard,

6.1.2. Stability and Shelf Life Validation

Stability and or clinical stability according to the product type.
Under the conditions of 0 ~ 35 ° C and humidity of 35% ~ 75%, 15 batches were used to verify the shelf life of 3 batches. The shelf life of the product under the recommended storage conditions is specified to be at least 2 years from the date of production.
The product aging verification report is shown in Appendix 10: Product Aging Report;

6.1.3. Physical, Chemical Testing, Microbiological (if applicable) - Biocompatibility Report

Intended use of the product According to the requirements of ISO 10993, the product is in contact for a period of time, and the product is only in contact with intact skin. It needs to detect 3 cytotoxicity, skin irritation experiments, and skin sensitization experiments.

Test	Test details	Conclusion
Cytotoxicity for Tape	Cytotoxicity test as per EN ISO 10993-5: 2009 ;	No cytotoxic effects should SSMT-R-2022-01420-01B
skin sensitization for Tape	Skin sensitization test as per EN ISO 10993-10: 2010 ;	No sensitization SSMT-R-2022-01420-02B
skin irritation for Tape	Skin irritation test as per EN ISO 10993-10: 2010 ;	No stimulation SSMT-R-2022-01420-03B

Note: The test report is annex 11： Biocompatibility test report;

6.1.4. Electrical Safety and Electromagnetic Compatibility

Not applicable

The product has no power connection；

6.1.5. Software Validation

Not applicable

Product does not contain software

6.2 Clinical Evaluation Report

This Clinical Evaluation document is prepared in accordance with the requirements stated under Article 61 of Medical Device Regulations, and with reference to the MEDDEV 2.7/1 Rev. 4 (MEDDEV) guidelines on medical devices entitled “Clinical Evaluation: A Guide for Manufacturers and Notified Bodies” drafted by the European Commission. A copy of the evaluation report is enclosed in this Technical File.

or

A Clinical Evaluation for the device has been carried out according to Article 61 of the Medical Device Regulation, and with reference to the Meddev 2.7/1 Rev. 4 (MEDDEV) guidelines, including data generated from post market surveillance (PMS) is described in the internal procedure DE-HSSG-CB-AA-05 . The clinical

evaluation and the clinical evidence on which it is based have been documented in the Clinical Evaluation Report.

Taken the intended use, the application and indication of the product group into consideration, it is concluded that the clinical safety and performance data demonstrate conformity with the general safety and performance requirements of the MDR.

The Clinical Evaluation (CER/ or CERD) is part of this Technical File and additional documents of the STED (see chapter 0. documentation in addition to STED).

7.Post Market Survaillance Documentaiton PMS, PMS Plan, PMCF, PSUR

Because the product belongs to Class I， PSUR is not applicable for Class I devices.

Post-Market Surveillance Plan shall be drawn up in accordance with Article 84 (MDR) to which the post-market surveillance system referred and based on. The post-market surveillance plan shall be set out in accordance to the requirement in Section 1.1 of Annex III in the MDR.

The Post Market Surveillance (PMS)and are well described in the internal procedure HTNT-CE-Tape, Post-marketing and internal process control methods describe vigilance and incident reporting.

The PMS data are part of the CERD, PMCF plan and data are part of this Technical File and an additional document of the STED .

See annex 13：HBNT-CE-003-04 PMS Plan(Tape) .

PSUR is not applicable for Class I devices.

8.List of Applied Standards

Standard	Description
EN ISO 10993-1:2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5-2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10-2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 14971-2012	Medical devices - Application of risk management to medical devices
EN 1041-2008	Information supplied by the manufacturer of medical devices (Incorporates Amendment A1: 2013)
EN ISO 15223-1-2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 9001-2015	Quality management systems – Requirements
ISO 13485-2016	Medical devices - Quality management systems - Requirements for regulatory purposes
MDR 2017-745	
MEDDEV.-2.7.1-Rev.3	
Company standards	

9.Documentation in addition to STED

Documentation of the Legal Manufacturer

Chapter	Document Name/ file name	Expiry date/ revision
7	Vigilance: Name of document.：ZZNQ-MP15 Alert system control procedure	2021.12.5

10.Document Change History Table

Revision	Changes Technical File [Date]	Document Name/ file name/ Chapter	Person
1	2022-8-7	Update documents according to MDR requirements	Wangyang
2			
3			