

CE Technical File Adhesive Bandage	File No: BT-CE-TF-1S-03_2.1
	Rev. No: A/2

Instruction for use

Product Name: Adhesive Bandage

File No.: BT-CE-TF-1S-03_2.1

Version: A/2

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Bestreat Safety & First Aid Solution Co., Ltd

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Revision history

Revision Chapter	Revision Content	Revision Reason	Revision Date	Revised By	Document No. & Version	Remark
/	First issued	/	2022.09.15	/	BT-CE-TF-1S-03-2.1 A/1	/
Chapter II	Add the trade name\ BASIC UDI-DI/ Catalogue number	Incomplete information	2024.01.15	Echo Yan	BT-CE-TF-1S-03-2.1 A/2	/

1.Product name

Adhesive bandage

Trade name: N/A

CND/EMDN CODE: M03030202 SKIN-SAVE BANDAGES

BASIC UDI-DI: 697570648111MY

Catalogue number: 500

2. Brief introduction

2.1 Adhesive bandage is Adhesive tape, absorbent layer, isolation layer. The backing material of the sterilized band-aid is a low-allergenic medical adhesive coated on a breathable PE film. The protective pad is made of non - textile non - woven fabric composite layer of polyethylene film. This product is a disposable sterile product and should be sterile.

Classification: According Annex VIII, Regulation (EU) 2017/745 4.NON-INVASIVE DEVICES
4.4 Rule 4

All non-invasive devices which come into contact with injured skin and mucous membrane are classified as:

---- class IS if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

The classification of the production is class IS

Conformity assessment route: Annex XI Part A of MDR

2.2 Patient populations: For adults, children, infants;

Intended user: Use by health care professional and lay person;

Duration of use or contact with the body: Less than 24h 【Contact duration: A-limited (≤24h)】

Its only for single use;

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2.3 Reference to previous and similar generations of the device

We do not hold the MDD certificate, and no sales at the moment.

The adhesive bandage is used for minor superficial wounds and abrasions of the superficial dermis and above. Provide a healing environment for superficial wounds and skin wounds.

Adhesive bandage is Adhesive tape, absorbent layer, isolation layer. The backing material of the sterilized band-aid is a low-allergenic medical adhesive coated on a breathable PE film. The protective pad is made of non - textile non - woven fabric composite layer of polyethylene film. This product is a disposable sterile product and should be sterile. The specification at above is common, we can also make the device per customer's special requirements, e.g. in different size. We develop the adhesive bandage base on the similar product which has been sold and widely use in the market, no previous and similar generations of the device was exist.

2.4 Planned variants

The planned variable is that the size will increase or decrease according to customer requirements. For the sizes, please refer to point 4 Models of product.

3. Intended Use

It is used for minor superficial wounds and abrasions of the superficial dermis and above.

4. Model and specification

4.1 Model: according to the material of sterilized band-aid, it can be divided into Elastic type, Waterproof type, Cotton fabric type, Breathablity type, Blister type.

4.2 Specifications: See Table 1.

Table 1 Specifications and dimensions of Adhesive bandage

Units: mm

Specification	length	Width	permissible error
60x100	60	100	±2%

5.Contraindications

None

6.Sterilization

Steam sterilization or Ethylene oxide sterilization (EO sterilization)

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7.Precautions

- 1) This product is a disposable product
- 2) Do not use expired products
- 3) It is strictly prohibited to use if the inner package is damaged
- 4) Disinfect the wound before use, and do not touch the protective pad with your hands after unpacking.

8.Warning

- 1) This product is a disposable product
- 2) Do not use expired products
- 3) It is strictly prohibited to use if the inner package is damaged
- 4)Disinfect the wound before use, and do not touch the protective pad with your hands after unpacking.

9.Instruction for use

Clean the wound surface, tear off the release paper of the product, stick the protective pad on the wound surface, fix the position of the adhesive backing material, and tighten appropriately.

10.Major raw materials

Adhesive tape, absorbent layer, isolation layer

The chemical composition:

Adhesive tape: Viscose42%+58% Polyester fiber

Absorbent layer: Polythene15%+Viscose60%+Polyester fiber25%

Isolation layer: Plantfibre100%

11.Performance parameter

Products should be neatly cut edges, clean surface, no stains, damage; Water absorption is greater than or equal to 200%, the peel strength is greater than or equal to 1. 0N/cm.

12.Storage conditions

Should be stored in a well-ventilated room without corrosive gas.



13.Transport Conditions

Sunscreen and rainproof during transportation












14.shelf life of product

5 years and 3 months

【Definitions of graphics, symbols, abbreviations】

	DO NOT REUSE		USE BY
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	BATCH CODE		" CE " Marking
	DATE OF MANUFACTURE		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	MANUFACTURER	MD	Medical devices
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	STERILIZED USING ETHYLENE OXIDE		STERILIZED USING STEAM OR DRY HEAT
	DO NOT USE IF PACKAGE IS DAMAGED		SINGLE STERILE BARRIER SYSTEM

【Manufacturer Information】



Manufacturer

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