Instruction for use

Product Name:	Absorbent Nonwoven Compress
File No.:	BT-CE-TF-IS-02_2.1
Version:	A/2

Complied by:	Echo Yan	Date:	2024.01.15
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Bestreat Safety & First Aid Solution Co., Ltd

CE Technical File Absorbent Nonwoven Compress

Rev. No: A/2

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Revision	Revision Content	Revision	Revision	Revised	Document No. &	Remark
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					BT-CE-TF-1S-02-	
/	First issued	/	2022.09.15	/	2.1	/
					A/1	
Chantan	Add the trade name	Incomplete		Echo	BT-CE-TF-1S-02-	
Chapter	BASIC UDI-DI/	Incomplete information	2024.01.15		2.1	/
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Revision history

1.Product name

Absorbent Nonwoven Compress

In addition, the production has another trade name: Eye Compress, Non-Woven Absorbent Pad, Trauma Pad, Wound Compress Pad, Low Adherent Dressing, Non-Woven Pad, Non-Woven ball.

EMDN CODE: M0202030101 NON-WOVEN SPONGES, NOT RX, STERILE

BASIC UDI-DI: 697570648110MW

Catalogue number: 800

2. Brief introduction

2.1 Absorbent Nonwoven Compress is made from nonwoven fabrics, they are cutting and folded into block or piece. they are aseptic.

Classification: Class Is /Rule 4 according to Annex VIII. According to Annex VIII Classification criteria, Medical Devices Regulation 2017/745/EC

Rule 4:

All non-invasive devices which come into contact with injured skin:

- are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,

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;

2.3 Reference to previous and similar generations of the device

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

Absorbent Nonwoven Compress is intended to clean skin or wounds, absorb exudates from the body, be used as a mechanical barrier for injury skin.

Absorbent Nonwoven Compress is made from nonwoven fabrics, they are cutting and folded into block or piece. they are aseptic. 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 absorbent nonwoven compress 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

These productions are intended to clean skin or wounds and absorb exudates from the body, be used as a mechanical barrier for injury skin.

4. Models and specification of product

	open si	ze(cm)	fold si	ze(cm)	
Specifications	Length	Width	Length	Width	
	±0.5	±0.5	±0.5	±0.5	
	Non-Wov	en Pad			
5cm x 5cm-4p	10	10	5	5	
5cm x 5cm-6p	15	10	5	5	
5cm x 5cm-8p	20	10	5	5	
7.5cm x 7.5cm-4p	15	15	7.5	7.5	
7.5cm x 7.5cm-6p	22.5	15	7.5	7.5	
7.5cm x 7.5cm-8p	30	15	7.5	7.5	
10cm x 10cm-4p	20	20	10	10	
10cm x 10cm-6p	30	20	10	10	
10cm x 10cm-8p	40	20	10	10	
Nor	Non-Woven absorbent Pad				
10cm x 10cm-8p	40	20	10	10	
20cm x 20cm-4p	40	40	20	20	
20cm x 20cm-6p	60	40	20	20	
20cm x 20cm-8p	80	40	20	20	
20cm x 30cm-4p	40	60	20	30	
20cm x 30cm-6p	60	60	20	30	

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Rev. No: A/2

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5.Contraindications

Nonwoven allergies are forbidden to use

6.Sterilization

Steam sterilization or Ethylene oxide sterilization (EO sterilization)

7.Precautions

- 1) This product is a disposable product.
- 2) Do not use expired products
- 3) Damaged inner packing is strictly prohibited.
- 4) The used compresses should be put into the medical dustbin.

8.Instruction for use

- 1) Tear off along the upper edge of the inner package to remove the product.
- 2) The center of the compress is aligned with the wound surface,
- 3) The compress should be covered by bandage or dressing, etc.,
- 4) Wounds can be treated with iodophor, alcohol, etc.

9.Major raw materials

nonwoven fabric

The chemical composition: Viscose60%+ Polyester fiber40%

10.Storage conditions

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

11.Transport Conditions

Sunscreen and rainproof during transportation

12.shelf life of product

5 years and 3 months

[Definitions of graphics, symbols, abbreviations]

\otimes	DO NOT REUSE	22	USE BY
LOT	BATCH CODE	C € 0197	" CE " Marking

CE Technical File	File No: BT-CE-TF-1S-02_2.1
Absorbent Nonwoven Compress	Rev. No: A/2

	DATE OF MANUFACTURE	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	MANUFACTURER	MD	Medical devices
×	KEEP AWAY FROM SUNLIGHT	آ	KEEP DRY
STERILEEO	STERILIZED USING ETHLENE OXIDE	STERILE	STERILIZED USING STEAM OR DRY HEAT
	DO NOT USE IF PACKAGE IS DAMAGED	\bigcirc	SINGLE STERILE BARRIER SYSTEM

[Manufacturer Information]



Manufacturer

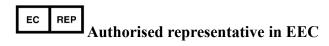
Name: Bestreat Safety & First Aid Solution Co., Ltd.

Address: Room 401, 4th Floor, Building 2, Bonded Zone, No.378 Gexin Avenue, Dongxihu District, Wuhan, 430040 Hubei, P.R. China

Contact person: Echo Yan

E-mail: qm@bestreatkit.com

(Authorized Representative Information **)**



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