

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

Instruction for use

Product Name: Absorbent Nonwoven Compress

File No.: BT-CE-TF-IS-02_2.1

Version: A/2

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

<p align="center">CE Technical File Absorbent Nonwoven Compress</p>	File No: BT-CE-TF-1S-02_2.1
	Rev. No: A/2

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-02-2.1 A/1	/
Chapter II	Add the trade name\ BASIC UDI-DI/ Catalogue number	Incomplete information	2024.01.15	Echo Yan	BT-CE-TF-1S-02-2.1 A/2	/

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 ($\leq 24h$)】

Its only for single use;

2.3 Reference to previous and similar generations of the device

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

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

Specifications	open size(cm)		fold size(cm)	
	Length	Width	Length	Width
	±0.5	±0.5	±0.5	±0.5
Non-Woven 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
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

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

20cm x 30cm-8p	60	60	20	30
30cm x 30cm-4p	60	60	30	30
30cm x 30cm-6p	90	60	30	30
30cm x 30cm-8p	120	60	30	30
40cm x 40cm-4p	80	80	40	40
40cm x 40cm-6p	120	80	40	40
40cm x 40cm-8p	160	80	40	40
50cm x 50cm-4p	100	100	50	50
50cm x 50cm-6p	150	100	50	50
50cm x 50cm-8p	200	100	50	50
Non-Woven ball				
25mm	12	15	DIN20-30mm	
30mm	15	15	DIN25-35mm	
40mm	20	20	DIN35-45mm	
50mm	20	30	DIN45-55mm	
Low Adherent Dressing				
5cm x 5cm	5	5	\	\
5cm x 7.5cm	7.5	7.5	\	\
7.5cm x 10cm	7.5	10	\	\
10cm x 10cm	10	10	\	\
Absorbing Pad				
5" x 9"	5"	9"	\	\
8" x 10"	8"	10"	\	\
10cm x 10cm	10	10	\	\
10cm x 20cm	10	20	\	\
20cm x 20cm	20	20	\	\
20cm x 30cm	20	30	\	\
20cm x 40cm	20	40	\	\
Trauma Pad				
20cm x 30cm	20	30	7.5	10
50cm x 50cm	50	50	9	9
60cm x 40cm	60	40	9	8
60cm x 80cm	60	80	9	9
80cm x 120cm	80	120	10	10
Eye compress				
5.5cm x 7.5cm	5.5	7.5	\	\

5.Contraindications

Nonwoven allergies are forbidden to use

<p align="center">CE Technical File Absorbent Nonwoven Compress</p>	File No: BT-CE-TF-1S-02_2.1
	Rev. No: A/2

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】

	DO NOT REUSE		USE BY
	BATCH CODE		" CE " Marking

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

	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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