

Instruction for use

Product Name: Cotton Tips

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Version: A/2

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Bestreat Safety & First Aid Solution Co., Ltd.

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-05-2.1 A/1	/
Chapter II	Add the trade name\ BASIC UDI-DI/ Catalogue number	Incomplete information	2024.01.15	Echo Yan	BT-CE-TF-1S-05-2.1 A/2	/

1.Product name

Cotton tips

Trade name: N/A

CND/EMDN CODE: M020199 COTTON GAUZES - OTHERS

BASIC UDI-DI: 697570648104N3

Catalogue number: 900

2. Brief introduction

2.1 The Cotton tip is made of absorbent cotton wrapped around one or both ends of a thin wooden or plastic rod. The Cotton tips is packaged and sealed in plastic film. The production is for single use and should be discarded after use.

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 ($\leq 24h$)】

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.

The Cotton tip is used for wound debridement care, sticky detoxifier, etc. for single use. And is made of absorbent cotton wrapped around one or both ends of a thin wooden or plastic rod. The Cotton tips is packaged and sealed in plastic film. The production is for single use and should be discarded after use. 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 cotton tip 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 and specification.

3. Intended Use

Used for wound debridement care, sticky detoxifier, etc. for one-time use.

4. Model and specification

1)Model:

According to the material of the cotton swab stick , they are divided into Wooden stick swab, Plastic stick swab, Bamboo stick swab, Paper stick swab.

2)Specification:

Specifications	Tolerance (cm)
7.5cm	±1
8cm	
10cm	
12cm	

5. Contraindications

Cotton allergies are forbidden to use.

6.Sterilization

Steam sterilization or Ethylene oxide sterilization (EO sterilization)

7.Precautions

- 1) For single patient use only.
- 2) Store in a dark, cool and dry place.

8.Warning

- 1)The product can be used only once, should be used immediately after opening the package and destroyed afterwards; if it is reused, the users or patients can be infected, patients have adverse reactions such as irritation and sensitization.
- 2) The product finked or affected with damp cannot be used. It should locate in the place where is abstained from high temperature and high humidity, and from caustic gases, and have good dryness and ventilation.
- 3) The product must be used within the validity period.
- 4)According to classification of medical waste, wastes of the production are Infectious wastes. They shall be classified and divided into packages or containers.

9.Instruction for use

- 1) Open the package, take out the cotton swab, and don't touch the cotton tip
- 2) It is suitable for mechanical barrier and absorbing exudate.

10.Major raw materials

Absorbent cotton

The composition:

The swab head: Absorbent cotton100%

The swab rod: Wood(Birch100%)

11.Storage conditions

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






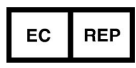








12.Transport Conditions

Sunscreen and rainproof during transportation

13.shelf life of product

5 years and 3 months

【Definitions of graphics, symbols, abbreviations】

	DO NOT REUSE		USE BY
	BATCH CODE		" CE " Marking
	DATE OF MANUFACTURE		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	MANUFACTURER		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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CE Technical File

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