

Product Name: One-piece Ostomy bag, with the opening for drainage (emptying)

Item No.: A1O2270



浙江爱乐保医疗科技有限公司
Zhejiang Ailebao Medical Technology CO.,LTD

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Purpose of use

- It is used for stoma cleaning, nursing, excreta collection and skin care around the stoma.
- It is a product used to stick on the stoma to collect excreta.
- The product is in good contact with skin on the area of application and intestinal cavity. (Non-sterile).

Specifications:

Bag size: 30*15cm(+/- 1cm);

Cutting size: 15-75mm;

Color: Skin color;

Filter type: Built-in round type activated carbon filter, for gas exhaust, to eliminate completely the odors;

Flange (sucker): Flexible, is an integral part of a bag, with special hypoallergenic hydrocolloid adhesive;

Drainage closure mechanism: By means folding(wrapping) the drainage ends of film by flat plates and securing with velcro;

Key benefits:

- Made of layers of high-strength raw materials
- Provides safety and protection against odors
- Hypoallergenic hydrocolloid adhesive support
- Secure adhesion
- Maximum skin protection
- Content (collected excreta) is hidden by layers of non-woven material.

Address: No. 599 Haijing Rd., Longgang City, Wenzhou, Zhejiang, China.

web: <https://ailebaomed.com/>

Classification and Conformity Routes

Classification

According to the Annex VIII of MDR, Rules 1, the product is subject to: Class I

Conformity Routes



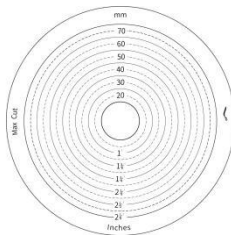
Conformity as per terms of Regulation (EU) 2017/745 Annex IV (Declaration of Conformity)

Certification

浙江爱乐保医疗科技有限公司
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- ISO 13485:2016
- CE
- FDA, CFDA

Carbon filter	
Velcro Closure	
Cutting hole size 15-75mm	

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LABELING:

QTY: 10 pieces/bag



Ostomy Collection Bags

Model No./Specification : A1O2270

Product : One piece system open

UDI-DI:

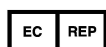
Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stoma specialist.
2. Valid for 3 years, please use within the validity period.
3. The packaging is damaged and it is forbidden to use it.
4. Single-use, destroy after use.



Zhejiang Ailebao Medical Technology Co.,Ltd.

2nd Floor, No.192 Xingxian Road, Longgang City, Wenzhou City, Zhejiang



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Tel:+49(0)89 189174474

Address:No. 599 Haijing Rd., Longgang City, Wenzhou, Zhejiang, China.

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Product Name: One-piece Urostomy bag

Item No.: A1U5145



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Zhejiang Ailebao Medical Technology CO.,LTD

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Purpose of use

- It is used for stoma cleaning, nursing, excreta collection and skin care around the stoma.
- It is a product used to stick on the stoma to collect excreta.
- The product is in good contact with skin on the area of application. (Non-sterile).

Specifications:

Bag size: 160*242cm; (Excluding urine mouth)

Cutting size: 13-45mm;

Color: White color;

From a single component (one-piece). The adhesive flange (sucker) made of the hydrocolloid.

Collector bag comes with built-in anti-reflux valve. The bags are drainable (with possibility of emptying). Back side surface (which is in contact with the skin) is made of non-woven material. Non-allergenic.

Key benefits:

- Made of layers of high-strength raw materials
- Hypoallergenic hydrocolloid adhesive support
- Secure adhesion
- Maximum skin protection

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Classification

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Conformity as per terms of Regulation (EU) 2017/745 Annex IV (Declaration of Conformity)

Certification

- ISO 13485:2016
- CE
- FDA, CFDA

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LABELING:

QTY: 10 pieces/bag



Urostomy Collection Bags

Model No./Specification : A1U5145

Product : One piece

UDI-DI:

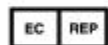
Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stoma specialist.
2. Valid for 3 years, please use within the validity period.
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