

Zhejiang Ailebao Medical Technology Co.,Ltd.

Ostomy Collection Bags

CE Technical File

File Code: ALB/CE-01

Version: A/0

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Issued: 30, Sep.2020

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1) Product list

Product No./Specification	A2O3260 series	A2C3160 series	A1C1160 series	A1O2260 series	A2U6260 series	A1U5160 series
Model	Product Name	Ostomy collection bag	Product Name	Ostomy collection bag	Product Name	Ostomy collection bag

2) 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 and intestinal cavity. (Non-sterile).

Structure

The product consists of a hydrocolloid sucker and collection bag.

Use for making pockets for storing human excrement containers, such as urine and feces mainly.

Capability

Indication:

Use for stoma cleaning, nursing, excreta collection and skin care around stoma and so on.

Contraindications:

Disable for the skin allergy.

3) Product Content (describing)

Domestic Certification:

Business license: 91330383MA2HDLK282

Certificate : CFDA

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)

Size

148*292mm

148*190mm

160*278mm


a. Raw material instruction

No.	Rawmaterial name	Purchase/ Manufacturing	Class	Supplier	Address	Note
1	EVO High barrier film	external purchase	A	Hangzhou Zhongsu Packaging Material Co. Ltd.	浙江余杭区钱江经济开发区康泰路 185 号	
2	PU Mist surface film	external purchase	A	Dongguan Jianguo environmental plastic film Co. Ltd.	东莞万江区新村社区村尾工业区	
3	Release liner	external purchase	A	Jiangsu Shuangxing Color Plastic New Materials Co.,Ltd.	江苏省宿迁市宿豫区井头乡双星大道北	
4	Nonwoven or reticulated fabric	external purchase	A	Noppon nonwoven fabric Co., Ltd.	杭州市余杭区临平余杭经济开发区宏达路 16 号	

b. Quality requirements(according to Product technical requirements)

1. Specification list:

Form 1: Size specification

Product No./Specification	A2O3260 series	A2C3160 series	A1C1160 series	A1O2260 series	A2U6260 series	A1U5160 series
Model	Two pieces system open	Two pieces system closed	Onepiece system closed	One piece system open	Two pieces urine bag	One pieces urine bag
Photo						

a) Size specification should obey form 1

b) Material: In raw material instruction

c) Biological properties.

i. Product make no skin irritation

ii. Product make no cytotoxicity

iii. Product make no delayed sensitive reaction

2. Product Photo of Sample

See, Form 1: Size specification

3. Certificates related factory &DOC---Appendix 8

4) Supplier Certificates--Appendix 9

5) BloodDeclaration

We, Zhejiang Ailebao Medical Technology Co.,Ltd.

2nd floor, No.192 Xingxian Road, Longgang City, Wenzhou City, Zhejiang
Province, China.

declare in our responsibility, that our products:

Product: Ostomy Collection Bags

Model / Specification:

A2O3260 series A2C3160 series

A1C1160 series A1O2260 series

A2U6260 series A1U5160 series ;

do not incorporate as an integral part:

a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EEC and which is liable to act upon the body with action ancillary to that of the device;

a human blood derivative referred to in 13.1. or 13.2., respectively, of Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council; and tissues of animal origin referred to in Regulation (EU) No 722/2012 (y/n), of the European Parliament and of the Council

Company representative name: Sheng Chunsheng

Company representative position: General manager

Representative signature: 盛春生

Place of Issue: Wenzhou, P.R.China

Date of Issue: 2020.08.28

6) DrugDeclaration

See above

This product does not contain any drug ingredients.

7) Declaration of Conformity

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Zhejiang Ailebao Medical Technology Co., Ltd.
2nd Floor, No.192 Xingxian Road, Longgang City,
Wenzhou City, Zhejiang Province, China, 325802.

Trademark: Ailebao

SRN: Not available yet

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN: Not available yet

Trade name: Ostomy Collection Bags

Product name: Ostomy Collection Bags

Product code / Catalogue number: A2O3260 series; A2C3160 series; A1C1160 series;
A1O2260 series; A2U6260 series; A1U5160 series.

Basic UDI: Not available yet

Classification acc. to MDR Ax. VIII: Class 1, rule 1

Applied Standard & Common Specification: EN ISO10993-1:2009; EN ISO10993-5: 2009;
EN ISO10993-10:2010; EN ISO 14971: 2012

Conformity assessment procedure: Annex II + Annex III of MDR;

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Sheng Chunsheng,
General Manager

Longgang, 04. 11. 2020

8) Annex I Essential Requirements--- Appendix1

9) Risk Management Report --- Appendix2

- a. Risk ManagementPlan
- b. Risk Analysis
- c. RiskEvaluation
- d. Risk Control
- e. Production and Post Productioninformation

10) Harmonised StandardList

Product-related StandardizationList

No.	Document Number	Version Number	Name ofDocument
1	ENISO14971	2012	Medical devices - Application of risk management to medical devices
2	EN 1041	2008+A1:2013	Information supplied by the manufacturer of medical devices
3	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
4	EN ISO10993-1	2009	Biological Evaluation of Medical Device-Part 1: evaluation and testing
5	EN ISO10993-5	2009	Biological Evaluation of Medical Device-Part 5: Test for invitro Cytotoxicity
6	EN ISO10993-10	2013	Biological Evaluation of Medical Devices –Part 10:Tests for irritation and delayed –type hypersensitivity

11) Labeling:

Labeling:01

QTY: 20 pieces/bag



Ostomy Collection BagsUDI-DI:

Product No./Specification : A2O3260 series

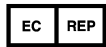
Model :Two pieces system open

Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stomatologist.
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
Province, China, 325802.



Name: MedPath GmbH.
Mies-van-der-Rohe-Steasse 8, 80807 Munich, Germany
Tel: +49(0)89 189174474
E-mail: info@medpath.pro..

QTY: 20 pieces/bag



Ostomy Collection BagsUDI-DI:

Product No./Specification : A2C3160 series

Model :Two pieces systemclosed

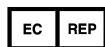
Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stomatologist.
2. Valid for 3 years, please use within the validity period.
3. The packaging is damaged and it is forbidden to use it.
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E-mail: info@medpath.pro..

QTY: 20 pieces/bag



Ostomy Collection BagsUDI-DI:

Product No./Specification : A1C1160 series

Model :One piece system closed

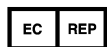
Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stomatologist.
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.



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E-mail: info@medpath.pro..

QTY: 20 pieces/bag



Ostomy Collection BagsUDI-DI:

Product No./Specification : A1O2260 series

Model :One piece system open

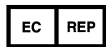
Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stomatologist.
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.



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E-mail: info@medpath.pro..

QTY: 20 pieces/bag



Ostomy Collection BagsUDI-DI:

Product No./Specification : A2U6260 series

Model :Two pieces urine bag

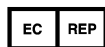
Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stomatologist.
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.



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E-mail: info@medpath.pro..

QTY: 20 pieces/bag



Ostomy Collection BagsUDI-DI:

Product No./Specification : A1U5160 series

Model :One pieces urine bag

Precautions:

1. Patients with purulent stoma should be used under the guidance of doctors or professional stomatologist.
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.
















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13) User Guide---- Appendix3

Symbol instruction

Symbol	Meaning	Symbol	Meaning
	Manufacturer		EU delegation information
	Date of manufacture		Use-by date
	Batch code		Keep dry
	Consult Instructions for use		Do not re-use
	CE mark		Do not use if package is damaged
	Keep away from sunlight		Non-sterile
	Medical device		

14) Clinical Evaluation (MEDDEV 2.7.1 Rev04)

Clinical evaluation report-- Appendix 4

15) Product Tests

Product Test Report –Appendix 5

Biocompatibility safety—Appendix 6

16) Post Production Procedure

CX-8.2.1-01 Customer satisfaction and feedback system control procedure

17) VigilanceProcedure

CX-9.0-01 AlarmingSystem Control Procedure

18) UMDNSCode

UMDNS Code: 16-459

19) Production Process and QualityControl--Appendix 7

20) Package

Packing case description:

1	size(Length × width × height)	(33*31*43) ±0.5cmProofing box	measurement
2	Style	Double corrugated	visual
3	Carton color	Yellow	visual
4	The material	Cowhide material	measurement
		Double corrugated board	measurement
5	Printing	Logo printing is clear, indentation is clear and easy to fold	visual

Packing box description

No.	material/specification		Requirements	Test method
1	medium box	Color	Color is consistent	visual
		Size	Check that the specifications meet the product requirements	measurement
		Printing	The text is printed clearly and error-free	visual

Packing bag description

No.	material/specification		Requirements	Test method
1	Ziplock bag	Color	Paper-plastic bag	measurement
		Size	The dimensions and specifications meet the requirements	measurement
		Printing	Uniform color, no damage	visual

Packing specification

Packing method: 1 / ziplock bag, 20 bags/box,
20 boxes/case count

The sealing way is uniform in color, good in sealing, no damage and pollution.

Adopt two layer packing, can be dustproof, moistureproof.

Attachment

Appendix 1: Essential Requirements CheckList

Appendix 2: Risk ManagementReport

Appendix 3: Directions for use

Appendix 4: Clinical evaluation report

Appendix 5: Product Test Report

Appendix 6: Biocompatibility safety

Appendix 7: Production Process and Quality Control

Appendix 8: Certificates related factory

Appendix 9: Supplier Certificates

Appendix 10: MDD authorized representative agreement