	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	1

1. Packaging

The Disposable drainage device is packaged by medical dialysis paper suction box of bacteria resistance consisting of PET (Polyethylene terephthalate) and medical adhesive dialysis paper.

Damaged packaging may indicate the presence of unsafe product and the product should not be used and should be returned. Once opened, the product should never be re-sterilized or re-used.

2. Samples of Labeling

2.2.1 Label Description

This section includes labeling information for the Disposable drainage device manufactured by SHANDONG GRED MEDIC CO., LTD.

Labeling system for CE marked for the Disposable drainage device is composed of the sticker (or print) on medical adhesive paper and carton box.


The symbols used in the indications are conforming to EN980、EN ISO 15223-1:2016

- 1) Medical dialysis paper suction box of bacteria resistance contain information about product, manufacturer and EC representative.
- 2) Carton box contain information about product, manufacturer and EC representative.

2.2.2. Label description of External drainage system for print on package

(medical dialysis bag of bacteria resistance)


- (1) Product name
- (2) CE mark and identification number of Notified Body
- (3) Manufacturer mark
- (4) EU Representative
- (5) Attention, see instructions for use
- (6) Temperature limitation
- (7) Do not reuse
- (8) Sterilization method

	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	2

- (9) Consult instruction for use
- (10) Lot number
- (11) Expiry date
- (12) Do not re-sterilize
- (13) Do not use if package damaged



Address: No. 70, Jiashan Road, Torch Hi-Tech Science Park, Weihai,
Shandong, China
Tel: 0086-631-5684168 Fax: 0086-631-5690295

Product: Disposable drainage device  :

Model:  :



Type:



SUNGO Europe B.V.
Address: Olympisch Stadion 24, Amsterdam 1076DE, The Netherlands
Tel: 0031-08-5029 0204 Fax: 0031-08-5029 0204

2.2.3. Label description of the External drainage system for sticker or print on paper box

- (1) CE mark and identification number of Notified Body.
- (2) Storage condition
- (3) Method of sterilization
- (4) Do not re-sterilize
- (5) Do not reuse
- (6) Attention, see instruction for use
- (7) Don't use when packing damaged

 	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	3

- (8) Product name
- (9) Quantity of External drainage system
- (10) Manufacturer
- (11) EC Representative
- (12) Date of manufacture
- (13) Lot number
- (14) Expiry date (until year and month)



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2797

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Shandong, China

Tel: 0086-631-5684168

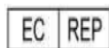
Fax: 0086-631-5690295

Product: Disposable drainage device  :

Model:  :

Type:  :

QTY: X/BOX



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2.2.4. Label description of the External drainage system for sticker or print on carton box

- (1) CE mark and identification number of Notified Body.
- (2) Storage condition
- (3) Method of sterilization

 	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	4

- (4) Do not re-sterilize
- (5) Do not reuse
- (6) Attention, see instruction for use
- (7) Don't use when packing damaged
- (8) Product name
- (9) Quantity of External drainage system
- (10) Manufacturer
- (11) EC Representative
- (12) Date of manufacture
- (13) Lot number
- (14) Expiry date (until year and month)



SHANDONG GRED MEDIC CO., LTD.



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Shandong, China

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Fax: 0086-631-5690295

Product: Disposable drainage device LOT :

Model:  :

Type:  :

QTY: X/CTN




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 大正医疗	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	5

2.2.5: Symbols on the label (EN980:2008)



= Do not reuse



= Don't use when packing damaged



= Manufacturer



= Attention, see instruction for use



=Consult instructions for use



= Temperature limitation



= Do not re-sterilize



= Lot number



= Date of manufacture



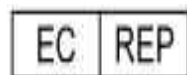
= Use until year & month (Expiration date)




=Method of sterilization



²⁷⁹⁷=CE-mark and identification number of Notified Body.
Certified according with MDD (93/42/EEC)




=Authorized representative in the EC

 大正医疗	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	6

2.3 Instruction for use(Rev. A/2)

This section includes information about description, indications(intended use, contraindications, precautions, direction for use or procedure) for the Disposable drainage device.

 大正医疗	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	7

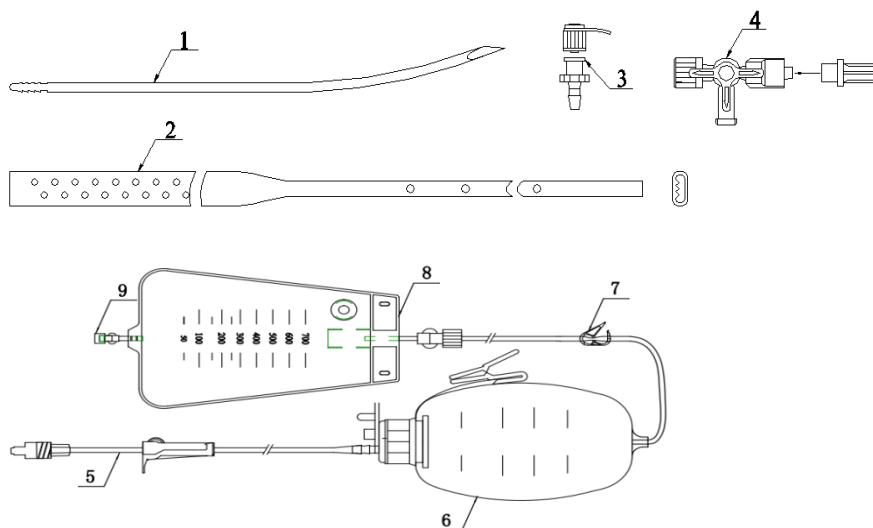
INSTRUCTIONS FOR USE of “Disposable drainage device”

1. DESCRIPTION

The Disposable Drainage Device consists of drainage tube (FLAT、CROSS、ROUND)、subcutaneous traction needle、locking joint and protecting cap of ruhr、three-way valve(optional)、connecting pipe (optional) and elastic absorber


The drainage tubes are radiographic, sterile and without pyrogen, and the amount of ethylene oxide residual shall be no more than 10 ug/g by ethylene oxide sterilization.

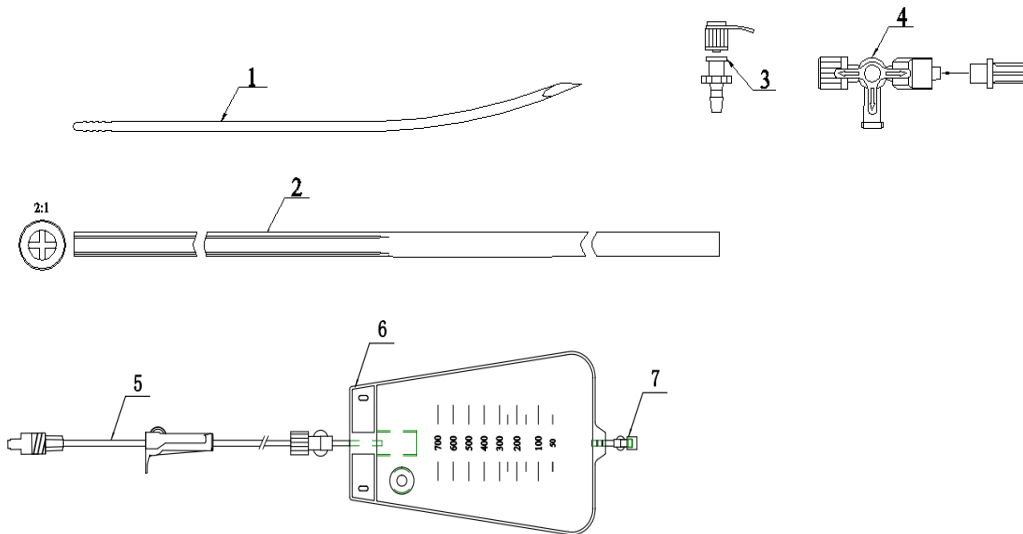
【Structural composition of product】



1. Subcutaneous traction needle; 2. Flat drainage catheter; 3. Luer lock connector and cap; 4. Three-way valve (optional); 5. Connecting pipe (optional); 6. Elastic lotion; 7. Stopper clip (optional); 8. Liquid bag; 9. Cap

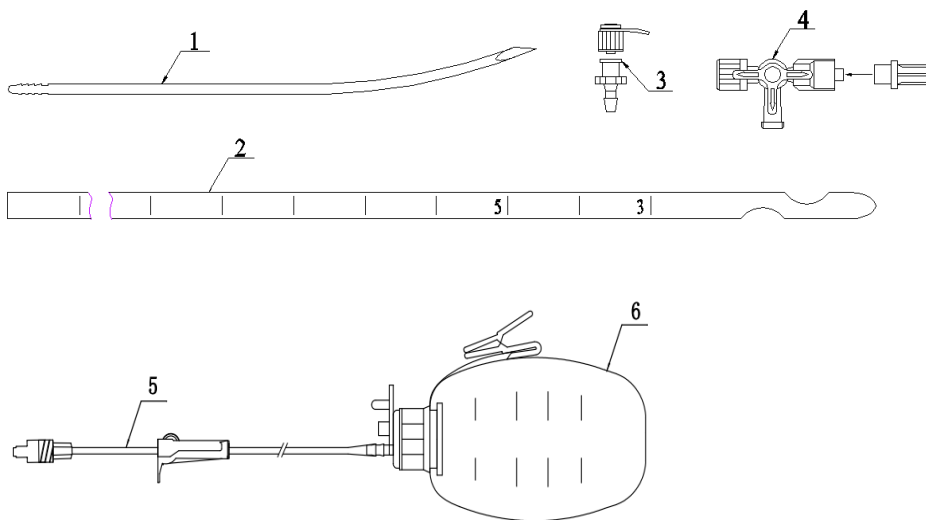
Figure 1 Structure chart of flat drainage device (Take the products with elastic pipette and liquid bag for example)

	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	8



1. Subcutaneous traction needle; 2. Cross drainage cathere; 3. Luer lock connector and cap; 4. Three-way valve (optional); 5. Connecting pipe (optional); 6. Liquid bag; 7. Cap

Figure 2 Structure chart of cross drairage device





1. Subcutaneous traction needle; 2. Cross drairage catheter; 3. Luer lock connector and cap; 4. Three-way valve (optional); 5. Connecting pipe (optional); 6. Elastic pipette

Figure 3 Structure chart of round drainage device (take the product with elastic pipette for example)

2. INTENDED USE

The product is suitable for the drainage of hemorrhage and exudates in trauma, wounds and surgical wounds.

 	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	9

3. WARNINGS & CONTRAINDICATIONS:

3.1 The traction needle is sharp. Please take care of yourself.

3.2 It is forbidden to use the product if the single package is damaged or the validity period of sterilization expires.

3.3 It is for single use only. Destroy it after use. Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

3.4 Do not use the product in combination with other devices. Do not change the product's structure in the using process!

3.5 Treatment of the medical waste should conform to the requirements of the local laws and regulations.

3.6 The device lifetime to the user is supposed to be less than 15 days.

【Contraindications】

Disposable drainage device are not intended for use in, and are contraindicated for:

- patient with abnormal blood coagulation mechanism.

4 INSTRUCTIONS:

4.1 Open the sealed bag under hygienic conditions and check the components complete and intact.


4.2 Select a suitable drainage catheter, cut the drainage end according to the needs of drainage site, and place the catheter;

4.3 Fix the drainage catheter after successful catheterization (if subcutaneous sneak is required, subcutaneous traction needle can be used for guidance);

4.4 Squeeze and fix elastic pipette, and perform drainage.

4.5 It is for single use only. Destroy it after use.

5. STORAGE

 大正医疗	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	10

The product should be kept in the dry, cool, well ventilated and clean place with relative humidity not exceeding 80%, temperature of 0-35°C and free of corrosive gas. And the sterility period is 2 years.

6.Explanation of Symbols in the label



= Do not reuse



= Do not use in case of package damage



= Manufacturer



= Attention, see instruction for use



=Consult instructions for use



= Temperature limitation



= Do not re-sterilize



= Lot number



= Date of manufacture




= Use until year & month (Expiration date)



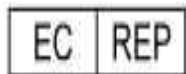
=Method of sterilization



₂₇₉₇=CE-mark and identification number of Notified Body.

 大正医疗	CE Technical File	Number	QA/DZ-TCF-SSYL-009
		Version	A/4
	Labeling and instruction for use	Date	2023.05.27
		Page	11

Certified according with MDD (93/42/EEC)



=Authorized representative in the EC

Manufacture: SHANDONG GRED MEDIC CO., LTD.

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EC REP: SUNGO Europe B.V.

Address: Olympisch Stadion 24, Amsterdam1076DE, The Netherlands

Tel: 0031-08-5029 0204 Fax: 0031-08-5029 0204

Notified Body: BSI (Notified Body no.: 2797)