

产品规格书

Product Specification

规格书编号 : LT201401010
Specification No: LT201401010

产品名称: 造口袋
Production Name: Ostomy Products

版本号 : 01
Revision No: 01

编 制 : 陈列飞
Issued by: Liefei Chen

审 核 : Lillian Zheng
Verified by: Lillian Zheng

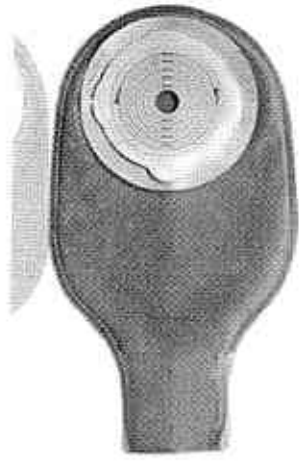
批 准 : 陈巧芳
Approved By: Qiaofang Chen

生效日期: 2014/01/01
Effective date: Jan. 1st 2014

记录保存期限 : 5 年
Record Retention: Five Years

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OSTOMY CARE

ONE-PIECE OPEN (HYDROCOLLOID ADHESIVE WITH SPUNLAC

NO: 4008, 4009

Data: 2017-04-13

View: 602

Product No	Size	Product Feature	pcs/box	boxes/case
4008	50mm	<ol style="list-style-type: none"> 1. Highly resistant CO-EX membrane 2. Hydrocolloid basic plate has strong viscosity, it can stick on the skin for 5 to 7 days. It is soft, hypoallergenic and friendly to skin. 3. The outer circle nonwoven fabric helps to fix the pouch and prevent exudate from leaking. 4. The active carbon filter has the odor removal function. 5. The drainable design is easy to empty and clean the pouch. 6. Convenient for operation. 	20 pcs/box	20 boxes/case
4009	60mm		20 pcs/box	20 boxes/case

Produk
Propus



Zhejiang Longterm Medical Technology Co., Ltd

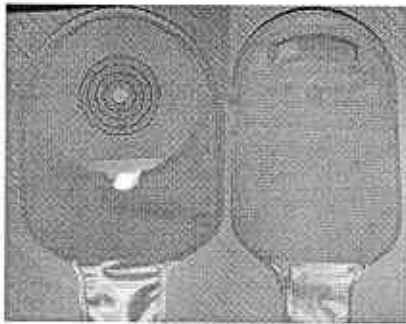
1. 产品规格要求 Product specification:

1.1 材料描述 MATERIAL DESCRIPTION:

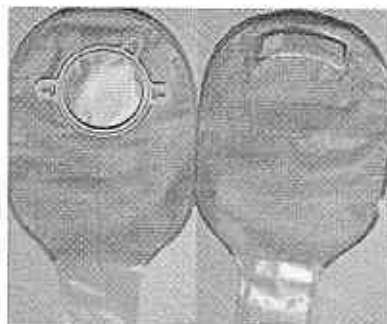
造口袋产品由底盘(纯水胶体底盘或水胶体外圈带无纺布底盘)、高阻隔膜、无纺布衬布或PE网格膜、活性炭过滤片组成。

Ostomy product is composed of barrier(hydrocolloid barrier or hydrocolloid with nonwoven edge skin barrier), highly resistant CO-EX film, nonwoven fabric or PE puncturing lining, carbon filters.

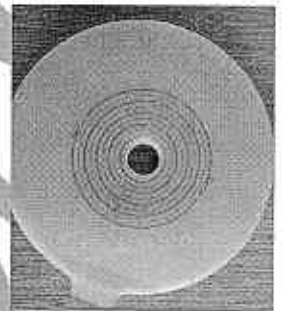
1.2 产品图片 PRODUCT PHOTOS:



One piece ostomy bag



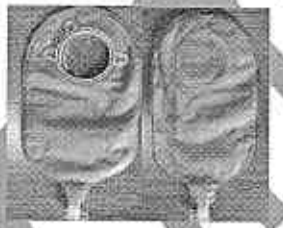
Two piece ostomy bag



Two piece barrier



One piece Urostomy bag



Two piece Urostomy bag

1.3 产品尺寸 Product Dimensions

Item	Size
One piece ostomy bag	50mm/60mm/70mm/80mm/90mm
Two piece ostomy bag	45mm/57mm/65mm/75mm/90mm
Two piece barrier	45mm/57mm/65mm/75mm/90mm
One piece Urostomy bag	50mm/60mm/70mm/80mm/90mm
Two piece Urostomy bag	45mm/57mm/65mm/75mm/90mm

备注：可根据客户的要求定制尺寸和形状。
Note: The product specifications can be available at clients' option.

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2 产品性能 Product performance

2.1 物理性能: PHYSICAL PROPERTIES

2.1.1 180°剥离力度: 背衬的剥离强度应不低于0.3N/cm。
180°peel strength. Peel strength of backing should be no less than 0.3N/cm.

2.1.2 密合性: 造口袋密合性能好, 无泄漏现象。
Leakage : Driving fit well, no leakage

2.1.3 连接牢固度: 造口袋各部件应连接牢固、不会脱落。
Connection : Good connection of each part, no fallen off.

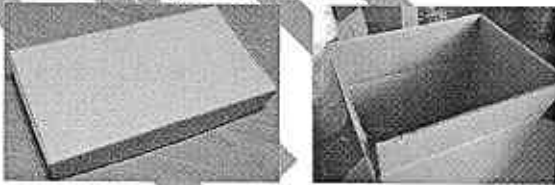
2.2 产品外观要求 Appearance

造口袋表面平整, 干净, 无污点, 无毛边
Surface should be smooth, clean, no stain, without burr.
底盘表面应光滑, 材质均匀无毛边。
Base plate(barrier) should be smooth, without burr.

3. 包装要求: PACKAGING

产品包装装入白色内盒, 再用出口专用 5 层瓦楞纸箱打包。

Several products packed in one white inner box. Finally, the several inner cases packed by export-use 5 layers carton.



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4. 贮存条件 Storage Condition

产品应贮存在干燥无腐蚀性气体且通风良好的室内。

Products should be stored in a dry and well-ventilated clean room and no corrosive gas .

5. 有效期 The period of validity

在规定的贮存条件下，自生产日起有效期 3 年

The product shall valid for 3 years from the manufacturing date, provided that it is kept under the stipulated storage conditions.

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Product Service

CERTIFICATE

No. Q1N 16 02 83478 016

Holder of Certificate: Zhejiang Longterm Medical Technology Co., Ltd.

Fengqing Road 618, Wukang Town
313200 Deqing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Zhejiang Longterm Medical Technology Co., Ltd.
Fengqing Road 618, Wukang Town, 313200
Deqing, Zhejiang, PEOPLE'S REPUBLIC OF
CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of
Hydrocolloid dressing, Alginate dressing,
Foam dressing and Silicone foam dressing,
Hydrogel dressing, Absorbent dressing,
Negative pressure wound therapy dressing,
Silicone net
Production and Distribution of
Sterile wound dressing, Skin closure strips,
Surgical drapes, Fecal collection bags,
Sterile wound plasters, Scar reducing emollient,
Ostomy bags and attachments, Infusion plasters,
Urinary drainage bag/collection bag,
Silicone tapes and Medical external fixation,
Medical tapes, Hydrocolloid patch,
Equipment cover, Sterile Hydrocolloid dressing

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1678205

Valid from: 2016-04-23

Valid until: 2019-04-22

Date, 2016-04-22

Stefan Preiß

Stefan Preiß



Deutsche
Akreditierungsstelle
G-ZM-11321-01-00

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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
 (Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 01 83478 024

Manufacturer: **Zhejiang Longterm Medical Technology Co., Ltd.**

Huancheng North Road 493
 Mo Gan Mountain
 National High-Tech District
 313200 Deqing, Zhejiang
 PEOPLE'S REPUBLIC OF CHINA



EC-Representative: **Lotus Global Co., Ltd.**

1 Four Seasons Terrace
 West Drayton, Middlesex
 London
 UB7 9GG
 UNITED KINGDOM

Product Category(ies): **Medical Tapes, Surgical Drapes, Infusion Plasters, Equipment Cover, Skin Closure Strips, Sterile Wound Plasters, Sterile Wound Dressing, Ostomy Bags and Accessories, Catheter Fixing Dressing, Hydrogel Eye Pad, Urostomy Bag, Urinary Collection Bag, Compression Hemostatic Dressing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH18782EXT01

Valid from: 2018-04-23

Valid until: 2023-04-22



S. Preiß

Date, 2018-02-01

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

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(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 01 83478 024

Facility(ies):

Zhejiang Longterm Medical Technology Co., Ltd.
Huancheng North Road 493, Mo Gan Mountain,
National High-Tech District, 313200 Deqing,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

