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## Urgent Field Safety Notice

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**Commercial name/Model: Wound dressing / NO.8,NO.9,NO.3**

**FSCA-identifier: 201701XK**

**Type of action:** *Recall the affected products and discard*

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Mar 23, 2017

**Attention:**

**Dear Sir or Madam,**

This letter is intended to provide you with information as following:

**Details on affected devices:**

The affected devices are 3 sizes of wound dressing: NO.8 medium size, NO.9 large size, and NO.3 extra large size. The label of the wound dressing was designed as below.



Distributed by: BCB Marine Ltd  
 Clydesmur Road, Cardiff, UK, CF24 2QS  
 Manufactured by: Taizhou Xinkang Medical Materials Co., Ltd.  
 No. 18, Wuzhou South Road, Taizhou, Jiangsu, China, 225300

LOT 2172  
 2020.9

STERILE R

0123






**9** PREMIUM  
**WOUND DRESSING**  
 Large Size  
 with conforming stretch bandage

When opening and applying the dressing, avoid touching/  
 contaminating the face of the sterile pad. Place sterile pad  
 over wound whilst retaining hold of the short end of bandage.  
Use opposite end of bandage to wrap wound and tie in a knot.

**KEEP IN A COOL DRY PLACE**  
**DO NOT USE IF WRAPPER OR SEAL IS DAMAGED**



These products have been sterilized before they were sold in the market. The sterilization was done by the qualified 3<sup>rd</sup> party provider, there have been no reported adverse incidents form using the products.

**Description of the problem:**

Taizhou Xinkang Medical Material Co., Ltd has been informed that there was a product symbol issue on the listed products in this documents. The affected products were labeled as “wound dressing”, the category of CE certificate includes “sterile gauze bandages”, while it doesn’t specifically say it includes “wound dressing”. The regulation doesn’t allow to sale the products with the product symbol “wound dressing”, because the category of CE certificate doesn’t specifically say it includes “wound dressing”.

The category of CE certificate includes the following products:

- Sterile gauze sponges
- Sterile gauze bandages
- Sterile absorbent cotton wool

- Sterile dental cotton roll
- Sterile cotton ball
- Sterile cotton tip applicator
- Sterile gauze rolls, Sterile gauze pads
- Sterile surgical towels
- Sterile non woven sponges
- Sterile triangular bandages
- First Aid Kit
- Sterile Zig-Zag absorbent cotton wool

The CE certificate copy is as follows:

IKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



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 15 07 56732 013**

<b>Manufacturer:</b>	<b>Taizhou Xinkang Medical Materials Co., Ltd.</b> No.18, Wuzhou ( South ) Road 225300 Taizhou, Jiangsu PEOPLE'S REPUBLIC OF CHINA	
<b>EC-Representative:</b>	<b>Shanghai International Holding Corp. GmbH (Europe)</b> Eiffestraße 80 20537 Hamburg GERMANY	
<b>Product Category(ies):</b>	<b>Sterile Gauze Sponges,          Sterile Gauze Bandage,          Sterile Absorbent Cotton Wool,          Sterile Zig-Zag Absorbent Cotton Wool,          Sterile Dental Cotton Rolls,          Sterile Cotton Ball,          Sterile Cotton Tip Applicator,          Sterile Gauze Rolls, Sterile Gauze Pads,          Sterile Surgical Towels,          Sterile Non-woven Sponges,          Sterile Triangular Bandage,          First Aid Kit</b>	

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.

<b>Report No.:</b>	SH15244EXT01	
<b>Valid from:</b>	2015-10-12	
<b>Valid until:</b>	2020-10-11	



**Date,** 2015-09-07  
Hans-Heiner Junker

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

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**Advise on action to be taken by the Hospital administrator:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.
2. Please stop using the device immediately.

**Advise on action to be taken by the distributor:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been delivered.
2. The Service Representative will contact you to replace the affected wound dressing.

**Transmission of this Field Safety Notice:**

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgment Form and return via E-mail or Fax.

**Contact reference person:**

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with

Organization: Taizhou Xinkang Medical Material Co., Ltd.  
Tel: 0086- 0523-86848901  
Fax: 0086-0523-86848738  
Email: [cindy@jsxk.cn](mailto:cindy@jsxk.cn)  
Cindy

This Notice has been notified the appropriate Regulatory Agency.

**Signature:**

General Manager

No. 18 Wuzhou (South) Road  
225300 Taizhou, Jiangsu P.R.China  
Tel: 0086-523-86848901  
Fax : 0086523-86848738  
Email : [cindy@jsxk.cn](mailto:cindy@jsxk.cn)

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Acknowledgement Form

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**Confirmation of Receipt of Field Safety Notice**

**Affected Products :**

**FSCA :**

**Type of FSCA :**

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**Please fill in this form and return this confirmation by E-mail or Fax immediately.**

**Fax:**

**Email:**

Name:

Tel. No.:

E-mail address:

Date and Signature:

Address of the Organization:



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## Appendix 1 List of Affected Devices.

We have identified that the wound dressing has been put into the UK market.  
The commercial name: No.8,No.9,No.3 wound dressing and Lot number: 2172.

### 1. List of ...which distributed with equipments

Country	Equipment S/N	Commercial name/Model	Water trap quantity	Distributor/Hospital	Contact person	Address	Telephone	Email

### 2. List of ....individual distributed

Country	Commercial name/Model	Affected quantity	Distributor/Hospital	Contact person	Address	Telephone	Email
UK	Wound Dressing (8#)	50000 rolls	BCB International Ltd	DEAN TINKLIN	Clydesmuir Rd Ind Est Cardiff CF24 2QS UK	+44 29 2043 3700	dpt@bcb.in.com
UK	Wound Dressing (9#)	54000 rolls	BCB International Ltd	DEAN TINKLIN	Clydesmuir Rd Ind Est Cardiff CF24 2QS UK	+44 29 2043 3700	dpt@bcb.in.com
UK	Wound Dressing (3#)	14000 rolls	BCB International Ltd	DEAN TINKLIN	Clydesmuir Rd Ind Est Cardiff CF24 2QS UK	+44 29 2043 3700	dpt@bcb.in.com

Note: (1). Lot No.2172. (2) All the products only exported to UK.