



YAFHO BIO-TECHNOLOGY CO., LTD.

Address: Rm202 & 3rd Floor, No. 81, Junfeng Road,
Huangpu District, Guangzhou, China.
TEL:86-20-85295649 FAX:86-20-85295797

Urgent FIELD SAFETY NOTICE

Date: 16-November-2016

YAFHO Reference: YA201601

Affected Device(s): ULTRASOUND PROBE COVER KIT WITH GEL

Contact:

Tel:86-20-85295649

Fax:86-20-85295797

Email: info@yafho.com

Site: www.yafho.com

To whom it may concern,

We, Yafho Wound Care have decided to recall the following product from the market.

ITEM NUMBER	ITEM NAME	BATCH NUMBER
654005	ULTRASOUND PROBE COVER KIT WITH GEL	20150701 / 20160201

Reason for the Recall

In the course of our post market surveillance activities we observed that the ultrasound probe cover kit with gel was found the Burkholderia multivorans, Burkholderia cenocepacia, Bacillus beringensis, Bacillus circulans inside, which pointed that the gel was the source of pollution. It may cause the risk of the patient harm. Out of an abundance of caution, we therefore voluntarily recalling the affected devices.

Actions to be taken

Our records have shown that your hospitals has received the affected batch as mentioned in the table above.

We kindly ask you to initiate the following activities immediately and with priority:

- A. Please identify, quarantine and return affected devices.
- B. Please do not use affected devices anymore.
- C. Please destroy the affected devices.
- D. Please confirm the receipt of this information.

Please pass the FIELD SAFETY NOTICE to all those who need to be aware of it within the organization.

If you have any question, please contact our distributor whose contact details are as below.

Company Name: Electronic Technicians est.

Tel: 4763108

Fax: 4786472



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Email: ete@ete.com.sa

Site: www.ete-ksa.com

Yafho Bio-Technology Co., Ltd

Ms Liang Haiyan

Position: Quality Manager

Nov.21st, 2016



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Appendix 1

CUSTOMER NO.: _____

FIELD SAFETY CORRECTIVE ACTION

ACKNOWLEDGEMENT FORM

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +86-20-85295797

E-MAIL: info@yafho.com

<input type="checkbox"/> We confirm receipt this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Filed Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory does include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. Return Authorization No _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:		
PRODUCT NUMBER	LOT NUMBER	QUANTITY

Include a copy of the completed Acknowledge Form in the completed acknowledgement Form in the returns package with the returned units

Ensure the RAN number is clearly visible on the returns package.

Please label returns as "Filed Action Returns"

Complete this Acknowledgement Form and return immediately by using the fax number or e-mail address above.

INSTITUTION NAME(EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	PHON/FAX
FORM COMPLETED BY:	STAMP
PRINT NAME: _____	
SIGNATURE: _____	
DATE: _____	