

Unit 3, 29 May Holman Drive
BASSENDEAN WA 6054
A.B.N. 81 604 095 758

Chief Executive Officer
<Insert Hospital Name>
<Insert Hospital Address>

Attention: 1. Stores Manager
2. Director of Nursing

URGENT MEDICAL DEVICE RECALL

Potential for Serious Infection

TGA Ref: RC-2017-RN-00631-1

MEDITECH SYSTEMS ASIA PACIFIC PTY LTD: ULTRASOUND PROBE COVER (Telescopic Folded with Gel)

Meditech Systems Asia Pacific Pty Ltd, is conducting a Hospital Level Recall, after becoming aware that the above product may be contaminated with *Burkholderia cenocepacia*.

The product details are:

All Ultrasound Probe Covers and gel supplied by Meditech which includes:

- 1. Ultrasound Probe Cover (Telescopic folded with gel), Part No: 88654012;
Order Code: 88654012;
Affected Lot No: 201701.**

Manufactured by:

Linmed Medical Co Ltd
No 3 Sixiang, 5 Street Douland Village, Zhongtang Town,
Dongguan City, Guangdong China

The Lot number is displayed on the middle right hand edge on the front of the packs- as per the pictures below.



AND

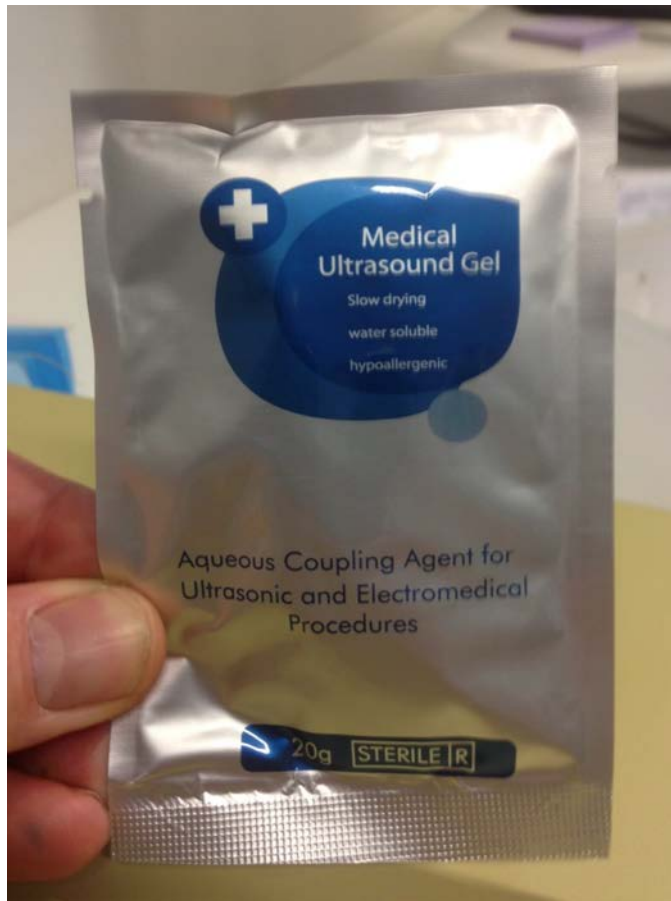
2. Products labelled Meditech and manufactured by:

Yafho Bio-Technology Co Ltd

3F 6 Plant Hengsheng Industrial Zone No 61 West Yicun Industry Road Luopu Street
Panyu District Guangzhou Guangdong China

AND

3. Any other manufacturer of Medical Ultrasound Gel as specifically pictured below – namely with a dark and light blue artwork combination.



Please inspect your stocks and quarantine all units from the manufacturers specified above. Then complete the attached Facsimile Reply Form and fax it to us so that we may arrange for your stock to be recovered or a credit note, issued.

Please complete the Facsimile Reply Form even if you have no stock which is subject to recall, as we require this information to reconcile this process.

If any of the recalled stock could have been transferred from your hospital to another, please immediately let that hospital know of the recall. It would be appreciated if you would then telephone us so that we can contact the hospital supplied from your hospital.

Please retain this letter in a prominent position for one month in case stock is in transit.

Meditech Systems Asia Pacific Pty Ltd sincerely regrets any inconvenience caused to your hospital. For information regarding this recall action, please contact Meditech Systems Asia

Pacific Customer Service on (08) 6162 9911 or John Paxman, Director Sales & Marketing on 0434 361 558.

This action is being conducted following consultation with the Therapeutic Goods Administration (TGA).

Yours Sincerely,

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12 May 2017

FACSIMILE REPLY FORM

TO: MEDITECH SYSTEM ASIA PACIFIC PTY LTD

ATTENTION: JOHN PAXMAN – DIRECTOR, SALES & MARKETING

FACSIMILE NUMBER: (08) 6162 9816

POSTAL ADDRESS: UNIT 3, 29 MAY HOLMAN DRIVE, BASSENDEN WA 6054

SUBJECT: RECALL OF ULTRASOUND PROBE COVER (Telescopic folded with Gel), Part NO 88654012,
Lot No: 201701

FROM: _____
<Insert Name of Hospital>

CONTACT PERSON: _____
(Please Print)

TELEPHONE NUMBER: _____

FACSIMILE NUMBER: _____

- We do/do not have stock which is subject to this recall
- Stock Received:
Lot No: _____ Qty (Boxes): _____
- Unused Stock subject to Recall (currently in quarantine):
Lot No: _____ Qty (Boxes/Units): _____

Any other relevant Details: _____

Signature: _____

Date: _____