URGENT FIELD SAFETY NOTICE

According to MEDDEV 2.12/1 rev. 8 ANNEX 5

Commercial name of product:	**Basin Liner**
Type of action:	Field Safety Corrective Action Follow up to Field Safety Notice dated 3 June 2014
Attention:	Theatre/Operating Room Manager/Quality Manager

Date: 14-July-2014

Dear Customer,

This field safety notice is to inform you of a voluntary recall involving Ecolab-Microtek Medical Basin Liners listed on the attached sheet. The content of this field safety notice supersedes a prior field safety notice sent on 3 June 2014.

Details of affected devices:
The product list is attached to this Field Safety Notice. All lot numbers are included in the scope of this Field Safety Notice.

Description of the problem:
During normal performance vigilance of the basin liner, it has been identified that a very low number of basin liners have small holes or cracks. These holes or cracks could, if present potentially compromise the sterile field.

Microtek Medical B.V.
a division of Ecolab
P.O. Box 234 7200 AE Zutphen The Netherlands
Hekkehorst 24, 7207 BN Zutphen The Netherlands
Tel. +31 (0)575 599 200 Fax +31 (0)575 599 299
www.ecolab.com
www.microtekmed.com

Actions to be taken by the user:
Please immediately examine your stock and promptly quarantine the product codes in the attached list. The scope of this recall includes all lot numbers.

In addition, if you have further distributed the products subject to this recall, please identify your customers and notify them at once of this product recall. Please monitor and reconcile the recall of product from your customers.

Please complete and return the enclosed response form by either fax or email as soon as possible, but no later than August 1, 2014.

Upon receipt of the completed response forms, we will issue a return material authorization (RMA) and ask that you return any unused product to Microtek Medical at the address listed in the attached form. We will issue a credit for the unused product upon receipt.

Transmission of this Field Safety Notice: (if appropriate)

This notice has been provided to:

Local Competent Authorities

MEDCERT GmbH - Notified Body CE 0482
Pilatuspool 2
20355 Hamburg
Germany

TÜV NORD CERT GmbH - Notified Body CE 0044
Langemarckstraße 20
45141 Essen
Germany

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the Field Safety Corrective Action.

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Please contact your local Customer Service or Sales Representative if you have any questions or concerns regarding this notification.

Sincerely,

Welmoed Clous
Vice President Regulatory Affairs EMEA

Ronald Groen
Director Supply Chain Operations EMEA
HEALTHCARE

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Response Form – Basin Liner

Please Fax or Email this Completed Response Form to:

TO:	Customer Service, Microtek Medical BV
FAX:	+31 575 599299
EMAIL:	custservnl@ecolab.com
RE:	Voluntary Medical Device Recall – Basin Liner

CUSTOMER NAME:	
CONTACT PERSON:	
CONTACT PERSON PHONE:	

Please check ALL appropriate boxes

☐ I have read and understand the recall instructions provided in the 11 July 2014 letter.

☐ I have checked my stock and have returned inventory consisting of _____ cases.

Any adverse events associated with recalled product?: ☐ Yes ☐ No

If yes, please explain:

_____

Please check the appropriate box(es) to describe your business:

☐ wholesaler/distributor ☐ retailer

☐ re-packer ☐ manufacturer

☐ hospital/medical facility ☐ medical laboratory

Please confirm the quantity of recalled product remaining available for use at your facility:

Product SKU	Lot Number(s)	Quantity Originally Shipped to Customer	Quantity of Product Available for Return and Credit
17700			
16700A			
3109N			
3109NT			
3108N			
33099			
9386001			
3309N			
TP1909A			
TP1909B			

PLEASE RESPOND BY AUGUST 1, 2014

MICROTEK MEDICAL PRODUCTS AFFECTED BY THIS NOTIFICATION

Part Number	Description
17700	Single Ring Basin Liner
16700A	Equipment Cover
3109N	Single Ring Basin Liner
3109NT	Single Ring Basin Liner, with tape
3108N	Single Ring Basin Liner
33099	NaCl Bowl Drape
9386001	Ring Basin Liner
3309N	Double Ring Basin Liner, Folded
TP1909A	Single Ring Basin Liner, Green
TP1909B	Single Ring Basin Liner, Green Unfolded

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