

URGENT FIELD SAFETY NOTICE

According to MEDDEV 2.12/1 rev. 8 ANNEX 5

Commercial name of product: Gamma Probe Cover
Product Code / REF: GPC396EU
Lot: D133381 & D140341

Type of action: Field Safety Corrective Action

Attention: Theatre/Operating Room Manager/Quality Manager

Date: 27-JAN-2015

Dear _____,

This field safety notice is to inform you of a Field Safety Corrective Action involving the Ecolab-Microtek Medical Gamma Probe Cover GPC396EU, Lot D133381 & D140341.

Details of affected devices:

Gamma Probe Cover, GPC396EU. Lot numbers in scope of this Field Safety Notice: D133381 & D140341.

Description of the problem:

During normal performance vigilance of the Gamma Probe Cover GPC396EU, Lot D133381 & D140341, potential leakage has been identified. This leakage, if present, could potentially compromise the sterile field.

Actions to be taken by the user:

Please immediately examine your stock and promptly quarantine the products of the affected Lots.

In addition, if you have further distributed the product subject to this Field Safety Notice, please identify your customers and notify them at once of this Field Safety Corrective Action. Please monitor and reconcile the actions taken on the affected lot from your customers.

Please complete and return the enclosed response form by either fax or email as soon as possible, but no later than **February 9, 2015**.

Upon receipt of the completed response forms, we will issue a return material authorization (RMA) and ask that you return any unused product of the affected batch 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:

This notice has been provided to:

Local Competent Authorities

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.

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

Sincerely,



Dieter Wirbals
Director Regulatory Affairs EMEA

Ronald Groen
Director Supply Chain Operations EMEA
HEALTHCARE



Response Form - Gamma Probe Cover GPC396EU, Lot D133381 & D140341

Please Fax or Email this Completed Response Form to:

TO:	Customer Service, Microtek Medical BV
FAX:	+31 575 599299
EMAIL:	custservnl@ecolab.com
RE:	Field Safety Corrective Action – Gamma Probe Cover GPC396EU

CUSTOMER NAME:	
CONTACT PERSON:	
CONTACT PERSON PHONE:	

Please check ALL appropriate boxes

- I have read and understand the instructions provided in the Field Safety Notice dated 27-JAN- 2015.
- I have checked my stock and have returned inventory consisting of _____ cases.

Any adverse events associated with the affected product?: Yes No

If yes, please explain:

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

- | | |
|--|---|
| <input type="checkbox"/> wholesaler/distributor | <input type="checkbox"/> retailer |
| <input type="checkbox"/> re-packer | <input type="checkbox"/> manufacturer |
| <input type="checkbox"/> hospital/medical facility | <input type="checkbox"/> 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
GPC396EU			

PLEASE RESPOND BY FEBRUARY 9, 2015

