Urgent Field Safety Notice

According to MEDDEV 2.12-1 rev. 8 ANNEX 5

Commercial name of the affected product: **Burr Hole Latex Free Probe Cover**

Type of action: **FIELD SAFETY CORRECTIVE ACTION (FSCA)**

Date: 10 July 2013

Dear Customer,

Details of affected devices:
Specific details of the affected product can be easily identified by the product name and SKU number and the batch numbers. See attached list of individual devices.

Description of the problem:

This is to inform you of a voluntary recall (Field Safety Corrective Action) involving **Ecolab-Microtek Probe Cover** products listed on the attached sheet. Enclosed you will also find a copy of the product labelling to assist with the identification of the product subject to this recall.

This recall has been initiated as the product batch numbers listed above did not undergo endotoxin (LAL) testing to the proper levels. If these products are used in contact with the Central Nervous System, patients might be exposed to endotoxin levels above prescribed limits. This type of exposure could elicit symptoms of bacterial endotoxinemia including an inflammatory reaction (fever, flu-like symptoms, cough with dyspnoea, headaches, nausea, vomiting) which, in rare cases, could lead to experienced neurological problems (generalised cramps, disturbances of sensibility, myalgia, tremor, bradykinesia, parkinsonism, difficulties in learning, etc.).

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.microtekmed.com

Advice on action to be taken by the user:

We began shipping these products in June 2008. **Please immediately examine your stock and promptly quarantine the batch(es) listed below**.

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. Notification may be accompanied by including a copy of this recall notification letter to further assist with your customer notifications. This recall should be carried out to the user level to prevent patient harm or illness.

Please complete and return the enclosed response form either by fax or email as soon as possible, but **no later than July 31, 2013**. We will follow up with you for an effectiveness check to ensure you understood these directions and followed through with our request.

Upon receipt of the completed response forms, we will issue a return material authorisation (RMA) and ask that you return any unused product listed above 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 passed on:

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 corrective action.

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Contact reference person:

Customer Service by phone 0031 575 599200 or email
custservnl@ecolab.com

The undersigned confirm that this notice has been notified to the appropriate Regulatory Agency.

Sincerely,

Youri Hiddes
Segment Marketing Manager Surgical EMEA
HEALTHCARE

Ronald Groen
Director Supply Chain Operations EMEA
HEALTHCARE

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Ecolab-Microtek Probe Cover products affected by this Recall

Product Name	SKU Number	Batch Numbers
Burr Hole Latex Free Probe Cover with Gel	PC3688 [20/cs]	D100131, D100341, D101521, D101861, D101871, D101881, D101891, D101901, D101931, D101941, D101951, D102491, D102531, D102651, D102731, D110691, D110831, D110841, D111021, D111111, D111221, D111381, D111451, D111651, D111801, D111961, D112091, D112231, D112371, D112511, D112661, D112791, D112911, D113061, D113211, D113341, D113481, D120111, D120261, D120401, D120551, D120661, D120811, D120811A, D120941, D121091, D121311, D121371, D121511, D121661, D121681, D122141, D122431, D122561, D122991, D130581, D81701, D81711, D82661, D83041, D83501, D90691, D90701, D91611, D92011, D92021, D92121, D92431, D92601, D92991, D93061, DA100051, DA100061, DA100341, DA100951, DA100971, DA101511, DA101521, DA102011, DA81931, DA82451, DA83011, DA83031, DA83241, DA91131, DA91141, DA91601, DA92881
Burr Hole Latex Free Probe Cover with Gel	PC3688EU [20/cs]	126429V,126602V, 126611V, 126612V, 126613V, 126614V, 127176V, 127182V, 127331V, 127382V, 137533V, 137826V, 137967V, 137666V, 137787V, 137817V
Burr Hole Latex Probe Cover with Gel	3688 [20/cs]	D102471, D102661, D102701, D110831, D111101, D111151, D111231, D111441, D112301, D112851, D112991, D113551, D120821, D121181, D121951, D122421, D130171, D130381, D82321, D82871, D83261, D90261, D91671, DA102491, DA90491, DA90621, DA91061, DA91671
Burr Hole Latex Probe Cover with Gel	3688UK [20/cs]	D101931, D101981, D102471, D110561, D111801, D112301, D112511, D112991, D113421, D120191, D120651, D121521, D122221, D123401, D130171, D130311, D130431, D82061, D82321, D82871, D83371, DA101891, DA81561, DA82061, DA85161

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ECOLAB®

Recall Response Form – Burr Hole Probe Covers

Please Fax or Email this Completed Response Form to:

TO:	Noel Vella, Quality Assurance Manager, Ecolab–Microtek
FAX:	+31 575 599299
EMAIL:	Noel.Vella@ecolab.com
RE:	Voluntary Medical Device Recall – Probe Covers

Please complete ALL sections listed below:

CONTACT NAME:	
PHONE #:	

Please check ALL appropriate boxes

☐ I have read and understand the recall instructions provided in the July 10, 2013 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
☐ re-packer
☐ hospital/medical facility
☐ retailer
☐ manufacturer
☐ 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
PC3688 [20/cs]			
PC3688EU [20/cs]			
3688 [20/cs]			
3688UK [20/cs]			

Please respond by July 31, 2013

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