

28<sup>th</sup> November 2019

***Dear Healthcare Professional Letter***

Dear Healthcare Professional,

cc: Chairman Medical Board and relevant Head of Departments

FSCA Ref No: **HSA 600:41/01-335/19/03\_50**.

Our supplier, USF Healthcare, has proactively taken the decision to recall the UNISEPTA FOAM 2, detergent disinfectant products for surfaces. This product may have been contaminated with Burkholderia cepacia.

These bacteria are commonly found in water and pose no risk to the general population. However, immunocompromised patients are at higher risk of infection.

You will find enclosed the official Field Safety Notice and Annexes provided by USF Healthcare.

For precautionary reasons, we ask you to stop immediately using the recalled products that you may have in stock, as there is a risk they may be contaminated.

We ask you to isolate these products locally and notify us of the quantities you have in stock by sending us the attached completed response form by 10<sup>th</sup> December 2019.

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to *Ms Lily Quah* [REDACTED]. Alternatively, healthcare professionals may report the adverse events to the Medical Devices Branch, Health Products Regulation Group, HSA at Tel: 6866 1048, or report online at [www.hsa.gov.sg/ae\\_online](http://www.hsa.gov.sg/ae_online). Events that are reported to *Raydent Supplies (S) Pte Ltd* will be investigated and subsequently reported to HSA.

Please accept our apologies for the inconvenience it may have caused.

Yours Sincerely,

[REDACTED SIGNATURE]

*Ms Jean Chng*  
*General Manager*

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 CH-1225 Chêne-Bourg Switzerland  
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## ANNEX I CUSTOMER REPLY FORM

### 1. Field Safety Notice (FSN)

FSN Reference:  
 FSN\_USF\_SSP\_DISTRIBUTORS\_EN\_EX NON EU

FSN Date: November 8, 2019

Affected products: ***Please refer to Annex II***

### 2. Customer Details

Customer Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	
Print Name*	
Signature*	
Date*	

Mandatory fields are marked with \*

### 3. Customer action undertaken on behalf of Healthcare Organisation

- I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.
- I performed all actions requested by the FSN.
- The information and required actions have been brought to the attention of all relevant users and executed, including end customers in case of distribution of those products
- I have destroyed affected devices – number of devices destroyed is documented in the table below (proof of destruction have to be provided to close the current action to [vigilanceUSF@Ecolab.com](mailto:vigilanceUSF@Ecolab.com))

Device Commercial Name	Article Code	Batch N°	Packages Quantity (units)

- No affected devices are available for destruction
- Other Action (Define):

### 4. Return acknowledgement to sender

Email	<a href="mailto:VigilanceUSF@Ecolab.com">VigilanceUSF@Ecolab.com</a>
Postal Address	USF Rue François-Perréard 18 - PO Box 142 CH-1225 Chêne-Bourg Switzerland
Fax	+41 22 839 79 10
Deadline for returning the customer reply form	05/12/2019

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.  
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions