USF Healthcare S.A.
Rue François-Perréard 18
PO Box 142
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Tel +41 22 839 79 00
Fax +41 22 839 79 10
Email info@usfhc.com
Web usfhealthcare.com
TVA CHE-107.755.324

Customer Number
Healthcare Organization Name
Address

Urgent Field Safety Notice

Date: January 23, 2019

Object:

☒ *Batch recall*
☐ *Information and/or recommendations*

Affected product:

Device Commercial Name	Article Code	Packaging
UNISEPTA FOAM 2 WIPES	2476655MC	6 X 100 WIPES

Madam, Sir,

A microbial contamination source *(Burkholderia cepacia, negative gram)* has been identified and localized in an outsourced manufacturing process and has brought a potential bacterial contamination to some batches of manufactured wipes.
In case of contamination triggered by contaminated wipes, immunocompromised patients would be at greater risk of infection (pneumonia). Globally, the risk assessment for potential health hazard linked to the use of those wipes results in low risk for the patient and the user. It takes into consideration the products' indication, the absence of any adverse event report linked to the use of the wipes, the probability of infection occurrence and the results of additional investigations (limited survival time of the bacteria and sensitivity of this bacteria to antibiotics: piperacilline (PTZ) and ceftazidime (CZD)).

Corrective actions to eliminate the contamination source have been implemented and are being closely monitored.

For precautionary reasons, we ask you to no longer use any remaining units you may have in stock bearing the batch numbers documented in the enclosed appendix, as they may contain some contaminated wipes.

We would be grateful if you could acknowledge receipt of the present communication by returning at your earliest convenience - but no later than 28/02/2019 - the attached reply form duly completed and signed.
If applicable, the proof of product's destruction has to be provided to close the current action.

Your sales contact remains at your entire disposal for any question or assistance that you may need.

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The undersigns confirm that this notice has been reported to the appropriate Regulatory Agency.

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

Yours faithfully.

Catherine Parcevaux Fivel *Quality Manager*	Yves Mailliard *Materio-vigilance Responsible*	Bertrand Letartre CEO

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

This means, if you are a distributor, that this information has to be forwarded to any customers which was delivered with one of the affected batches.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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APPENDIX I

CUSTOMER REPLY FORM

1. Field Safety Notice (FSN)

FSN Reference number*: Customer code_Nom du client

FSN Date: *January 23, 2019*

Affected products: ***Please refer to appendix 2***

2. Customer Details

Customer Number	Customer Number
Healthcare Organization Name*	Healthcare Organization Name
Organization Address*	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 *

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3. Customer action undertaken on behalf of Healthcare Organization

☐ 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 has to be provided to close the current action)

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	vigilanceUSF@ecolab.com
Postal Address	USF Healthcare Rue François Perréard 18 1225 Chêne-Bourg Swizerland
Fax	+41 22 839 79 10
Deadline for returning the customer reply form*	**28/02/2019**

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.

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APPENDIX 2

AFFECTED PRODUCTS

Medical device name	Model	Reference number	Lot/batch number
UNISEPTA FOAM 2 WIPES	6 packs of 100 wipes	2476655MC	A00324S
			A02404S
			A25015S
			A26023S
			A26503S
			A28107S
			A28314S
			W02317S
			W02615S
			W06823S
			W12423S
			W15010S
			W20814S
			W24717S
			W25104S
			W29906S
			W34720S