D.M.D

Pavé du Moulin
59260 Lille-Hellemmes
Tel +33 3 20 67 67 67
Fax + 33 3 20 67 67 68
web *vigilance@anios.com*

To Healthcare Organisation Name
Address

URGENT
FIELD SAFETY NOTICE

Date: January 22, 2019

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

Affected product:

Device Commercial Name	Article Code	Packaging
DENTASEPT SH PRO WIPES	2477655EC	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. 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 on surfaces 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 not to use any longer 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.

D.M.D

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

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

Isabelle Prévost *Quality Manager*	Dr Monique Manche *Materiovigilance responsible*	Bertrand Letartre *CEO*
		

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation 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.

D.M.D

Pavé du Moulin
59260 Lille-Hellemmes
Tel +33 3 20 67 67 67
Fax + 33 3 20 67 67 68
web *vigilance@anios.com*

Healthcare Organisation Name
Address

APPENDIX I
CUSTOMER REPLY FORM

1. **Field Safety Notice (FSN)**

FSN Reference number: FSN_DMD_EN

FSN Date: *January 22, 2019*

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

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 *

D.M.D

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)

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	vigilance@anios.com
Postal Address	DMD Service qualité Pavé du Moulin 59260 Lille – Hellemmes - France
Fax	+33 3 20 67 67 68
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

APPENDIX 2

AFFECTED PRODUCT

Medical device name	Model	Reference number	Lot/batch number
DENTASEPT SH PRO WIPES	6 packs of 100 wipes	2477655EC	A00807S
			A08122S
			A20409S
			W04722S
			W10810S
			W20720S
			W20814S
			W26321S
			W28302S
			W29906S
			W34720S