

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: 22/01/19

Object:

- Batch recall
 Information and/or recommendations

Affected products:

Device Commercial Name	Article Code	Packaging
WIP'ANIOS PREMIUM	2088655BR /2088655C4 / 2088655C5	6 X 100 WIPES
WIP'ANIOS EXCEL	2446424C2 /2446424ZA	12X50 WIPES
	2446492GX	12X60 WIPES
	2446655C4 / 2446655C5 / 2446655CO / 2446655Y6	6 X 100 WIPES

Madam, Sir,

A microbial contamination source 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.


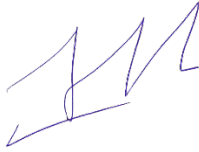

If applicable, the proof of product's destruction has to be provided to close the current action.

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 apologies for the inconvenience it may have caused.

Yours faithfully

Isabelle Prévost <i>Quality Manager</i>	Dr Monique Manche <i>Materiovigilance responsible</i>	Bertrand Letartre <i>CEO</i>
		

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.

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APPENDIX I CUSTOMER REPLY FORM

1. Field Safety Notice (FSN)

FSN Reference number: FSN_ANIOS_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 *

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	Laboratoires ANIOS 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 PRODUCTS

Medical device name	Model	Reference number	Lot/batch number	
WIP'ANIOS EXCEL	12 packs of 50 wipes	2446424C2	A00324S	
			A04420S	
			A06805S	
			A08122S	
			A21502S	
			A23602S	
			A25015S	
			A26503S	
			A28107S	
			W01716S	
			W02615S	
			W04204S	
			W07004S	
			W17911S	
			W19303S	
			W25811S	
			W26321S	
			2446424ZA	A00807S
			A23602S	
	12 packs of 60 wipes	2446492GX	A12712S	
			A20701S	
			A26215S	
			W33121S	
	6 packs of 100 wipes	2446655C4	A02518S	
			A02615S	
			A03211S	
			A04305S	
			A06805S	
			A07305S	
			A14911S	
			A16210S	
			A17404S	
			A18712S	
A19311S				
A20108S				
A20409S				
A23320S				
A23602S				
A24126S				
A28107S				
W00513S				
W03015S				
W04204S				
W06116S				
W06823S				
W07917S				
W08310S				
W09318S				

APPENDIX 2

AFFECTED PRODUCTS

Medical device name	Model	Reference number	Lot/batch number		
			W13516S		
			W14205S		
			W15010S		
			W15111S		
			W16619S		
			W17823S		
			W20720S		
			W21215S		
			W23603S		
			W23804S		
			W24717S		
			W25104S		
			W25811S		
		2446655C5			A00807S
					A02615S
					A06805S
					A16210S
					A19311S
					A28107S
					W03015S
					W04722S
					W12423S
					W25603S
					W29906S
					W34720S
					W35612S
		2446655CO			W03015S
		2446655Y6			A24126S
		WIP'ANIOS PREMIUM	6 packs of 100 wipes	2088655BR	A24712S
					A24829S
					W01618S
					W03821S
				2088655C4	
W26111S					
A00219S					
A18104S					
A19123S					
U08405S					
U11821S					
U17703S					
U21512S					
U25702S					
U32001S					
			W01618S		
			W03821S		
			W10912S		
			W18418S		
			W20304S		

APPENDIX 2

AFFECTED PRODUCTS

Medical device name	Model	Reference number	Lot/batch number
			W24313S
			W26111S
			W29209S
			W35214S
		2088655C5	A00219S
			A05504S
			A06105S
			A18104S
			A19123S
			A19725S
			U06705S
			U08405S
			U08412S
			U17605S
			U21404S
			U21512S
			U25602S
			U25702S
			U32001S
			U33419S
			U36401S
			W01618S
			W04410S
			W10104S
			W10912S
			W12905S
			W14705S
			W18418S
			W20304S
			W24313S
			W26111S
			W29209S
			W35214S