

Pavé du Moulin 59260 Lille-Hellemmes Tel +33 3 20 67 67 67 Fax + 33 3 20 67 67 68 web <u>vigilance@anios.com</u> Healthcare Organisation Name Address

URGENT FIELD SAFETY NOTICE

То

Date: 22/01/19

Object:

Batch recall

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 apologizes for the inconvenience it may have caused.

Yours faithfully

Isabelle Prévost	Dr Monique Manche	Bertrand Letartre
Quality Manager	Materiovigilance responsible	CEO
Huim	M	<u> </u>

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

<u>Affected products:</u> 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)

 $\hfill\square$ 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

WIPANIOS EXCEL 12 packs of 50 wipes 2446424C2 A004205 A08005S A08122S A21502S A23602S A22603S A22603S A226107S W002115S W02815S W02815S W02815S W02815S W02815S W02815S W02815S W17911S W19303S W226321S 2446424ZA A08907S A22001S A220701S A220701S A220701S A220701S A22615S A02615S A00307S A220701S A220701S A220701S A22615S A02615S A00301S A02615S A02615S A00305S A02605S A02518S A02005S A02615S A02311S A04305S A02805S A02805S A02805S A028005S A02805S	Medical device name	Model	Reference number	Lot/batch number
A04420S A06805S A06805S A28602S A28002S A28002S A28003S A28003S A28007S W01716S W002615S W002615S W07004S W17911S W19303S W25811S W26321S A28007S A28007S A28007S A28007S A28007S W19303S W25811S W19303S W26321S A00807S A28007S A28007S A28007S A28007S A28007S A28007S A28007S A28007S A0201S A0261SS A0305S A04305S A06805S A06805S A06805S A06805S A04305S A04305S A04305S <td< td=""><td></td><td></td><td></td><td></td></td<>				
A08122S A21502S A25015S A22603S A28017S W01716S W002815S W02815S W07004S W17911S W19303S W25811S W26321S A28002S 12 packs of 60 wipes 2446424ZA A00907S A22610S M233121S A22615S 6 packs of 100 wipes 2446655C4 A02615S A03211S A04305S A04305S A04305S A04305S A14911S A18712S A18712S A18912S A28107S W00513S A28107S W00513S W00305S A28107S W00823S W03215S W03215S W00823S W03215S W03215S				A04420S
A21502S A23602S A28015S A28017S A28017S W0215S W02045S W07004S W17911S W18303S W28211S W282811S W28321S A2602S 12 packs of 60 wipes 2446424ZA A00807S A22602S 412712S A22602S 12 packs of 100 wipes 2446692GX A12712S A26215S W33121S A02615S A02615S A0305S A04305S A07305S A18712S A18712S A18712S A18712S A24126S A22409S A22402S W000513S W000513S W000513S W000513S W000513S W000513S W00823S W008116S W00823S				A06805S
A23602S A25015S A2803S A28107S W01716S W0204S W07004S W19303S W28811S W28811S W28811S W2831S 2446424ZA A00807S A2802S 12 packs of 60 wipes 2446492GX A12712S A20701S A26215S W33121S 6 packs of 100 wipes 2446655C4 A02518S A0305S A14301S A04305S A148911S A04305S A14911S A16210S A14911S A2802S A220108S A14911S A2802S A22008S A12408S A12911S A2008S A2008S A24009S A28017S W00513S W00513S W00513S <				A08122S
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A06805S A07305S A14911S A16210S A17404S A18712S A19311S A20108S A20108S A2320S A23602S A24126S A28107S W00513S W004204S W06116S W06823S W07917S				
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A23602S A24126S A28107S W00513S W03015S W04204S W06116S W06823S W07917S				A20409S
A24126S A28107S W00513S W03015S W04204S W06116S W06823S W07917S				A23320S
A24126S A28107S W00513S W03015S W04204S W06116S W06823S W07917S				A23602S
W00513S W03015S W04204S W06116S W06823S W07917S				
W00513S W03015S W04204S W06116S W06823S W07917S				A28107S
W04204S W06116S W06823S W07917S				W00513S
W06116S W06823S W07917S				W03015S
W06823S W07917S				W04204S
W07917S				W06116S
				W07917S
W08310S				W08310S
W09318S				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	
			A24712S	
			A24829S	
WIP'ANIOS PREMIUM	6 packs of 100 wipes	2088655BR	W01618S	
			W03821S	
			W18418S	
		W26111 2088655C4 A00219	W26111S	
			A00219S	
			A18104S	
			A19123S	
				U08405S
			U11821S	
			U17703S	
			U21512S	
			U25702S	
				U32001S
			W01618S	
			W03821S	
			W10912S	
			W18418S	
			W20304S	
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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