Rev 2: February 2020
FSN Ref: AN-FSN-008 FSCA Ref: AN-FSCA-008

Date: 2023-04-27

Field Safety Notice
Wip'Anios Excel

For Attention of: Vigilance manager of the facility and the users of the affected products.

Dear customer,

We ask you to please review the information in this document and follow the appropriate actions outlined in section 3. Please return the reply form accompanying this FSN and return it to us as soon as possible.

Thank you for your cooperation and understanding.

Best regards,

ANIOS VIGILANCE

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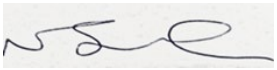
Field Safety Notice (FSN)

1. Information on Affected Devices	
1.	1. Device Type(s)
	Ready to use wipes
1.	2. Commercial name(s)
	Wip'Anios Excel
1.	3. Primary clinical purpose of device(s)
	Disinfectant wipes for invasive medical devices
1.	4. Device Model/Catalogue/part number(s)
	Wip'Anios Excel ○ REF: 2446655Y6 (6 x 100 wipes) ○ LOT: E16614S

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	In the framework of quality controls qualifications, we identified the presence of Achromobacter sp. in one of our products. As a precautionary measure we ask you to stop using the batches as specified in section 1.4 of this document until our investigations are finalized.
2.	2. Hazard giving rise to the FSCA
	Achromobacter sp. poses little medical risk to healthy people. However, it is a known cause of infections in hospitalized patients. Patients who have certain health problems like weakened immune systems, especially immunocompromised patients or in neonatal care, or chronic lung diseases, particularly those with cystic fibrosis, are at higher risk of infection.
2.	3. Probability of problem arising
	Taking into consideration the products' intended use, the probability of the bacteria infecting the at-risk patient population in case of use of a contaminated wipe is low.

3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Product ☒ Quarantine Product ☐ Return Device ☐ Destroy Device ☒ If you are a distributor, notify your customers of this Field Safety Notice ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None As a precautionary measure, we ask you to quarantine and to identify and physically isolate the products that you may have at your facility, while we complete our investigations.	
3.	2. By when should the action be completed?	Immediately
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Root-cause analysis including extensive testing and quarantining of potentially impacted products.	

4. General Information			
4.	1. FSN Type	New	
4.	2. Further advice or information already expected in follow-up FSN?	Yes	
4.	3. If follow-up FSN expected, what is the further advice expected to relate to:		
	We will inform about possible use or destruction instruction.		
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)		
	a. Company Name	Laboratoires Anios	
	b. Address	1 rue de l'Espoir, 59260 Lezennes, FRANCE	
	c. Website address	www.anios.com	
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.		
4.	6. List of attachments/appendices:	Annex I – FSN Reply Form	
4.	7. Name/Signature	Nicky Sullivan, (VP Quality and MPD)	
		Christian Jost, (Principal Specialist Regulatory Affairs)	

	Transmission of this Field Safety Notice
	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.