1 rue de l'Espoir
59260 LEZENNES - France
Tel +33 3 20 67 67 67
Fax + 33 3 20 67 67 68
E:mail *vigilance@anios.com*

Date : 29/11/19

Sir, Madam,

We want to inform you that a batch of the product ANIOSYME DD1 has been recalled. Please find enclosed the corresponding FSN.

As mentioned in this FSN, we have not found any microbial contamination in other batches of ANIOSYME DD1. However, with an abundance of caution, a restriction of use of this product has been applied. This product should only be used for the treatment of medical devices that will go through sterilization. This applies to all these other batches of ANIOSYME DD1 in stock as of November 16, 2019.

ACTANIOS P2 & ANIOSYME DD1+ being similar products to ANIOSYME DD1, we extend this restriction of use to these products you might have in stock as of November 16, 2019.

For ACTANIOS P2 which is still commercialised, this restriction will not apply to newly manufactured products that will be delivered to you, as we will conduct microbiological tests on every batch to ensure the quality of the products before distribution.

If you are reselling these products, we ask that you inform immediately your end customers.

Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 20/12/2019 - the completed, dated and signed letter.

We remain at your disposal for any question or assistance that you may need.

Yours faithfully,

Isabelle Prévost *Quality Manager*	Dr Monique Manche *Materiovigilance Contact Person*	Thomas Decoster *President*
		

Hereby,
- I confirm receipt of this letter and that I read and understood its content
- I attest performing all actions requested
- I confirm that I informed all relevant users, including end customers in case of distribution of this product

Healthcare organisation name: _____

Customer Number:_____

Name and function of signee: _____

Date and signature: _____

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web *vigilance@anios.com*

To Healthcare Organization Name
Address

URGENT
FIELD SAFETY NOTICE

Date: 14/11/19

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

Affected products:

Device Commercial Name	Packaging	Article Code	Batch Number
ANIOSYME DD1	4X5L	1200036	B28123S
	12X1L	1200095	

Madam, Sir,

We have identified that you received the product ANIOSYME DD1 for which we are recalling the batch B28123S as it does not comply with our quality expectations and may contain the gram-negative bacteria, *Sphingonomas Paucimobilis*.

This bacteria is a known cause of infections in hospitalized patients. Patients who have certain health problems like a weakened immune system, especially immunocompromised patients, or those with chronic diseases, are at higher risk of infection.

ANIOSYME DD1 is a pre-disinfectant detergent for medico-surgical instrumentation and thermosensitive medical devices (endoscopy equipment).

- For sterilizable equipment (autoclave or low temperature sterilization), the risk for patients is low, provided that the treatment steps of the devices are followed after the use of ANIOSYME DD1;
- In the absence of sterilization, the risk for the patients is increased but remains generally low (in the case of the use of the product ANIOSYME DD1 followed by a step of high-level disinfection).

We ask you to block and isolate these products. In addition, we need you to inform immediately your end customers and ask them to notify you of the quantities they have in stock. You will be required to collect the completed response form (Annex I) from your customers and share a consolidated form with us of all the products you have recalled to the following e-mail address: Vigilance@anios.com. Any quantity declared can be subject of verification.

We have not identified any contamination in other batches of ANIOSYME DD1. As a measure of precaution, we ask you nevertheless to limit the use of other batches of the product you might have in stock to the pre-disinfection of sterilizable equipment.

Corrective measures to eliminate the source of the contamination are being implemented and we are putting in place additional hygiene safety protocols.

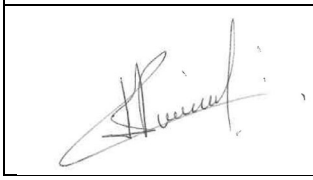
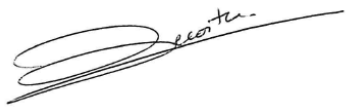
Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 10/12/2019 - the completed and signed reply form.

Your Anios representative will contact you to discuss the return of the recalled product you have in stock. We remain 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 *Quality Manager*	Dr Monique Manche *Materiovigilance Contact Person*	Thomas Decoster *President*
		

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.