FSN Ref: AN-FSCA-014_FSN_Master_EN_en_1 FSCA Ref: AN-FSCA-014

Date: 2025-08-22

Field Safety Notice
ANIOSYME SYNERGY 5

For Attention of*: Vigilance/Quality manager of the facility products.

Dear Customer,

We are reaching out to inform you of an important issue regarding the product Aniosyme Synergy 5 involving the following batch: H32619S.

Product Name	SKU	Batch Number
Aniosyme Synergy 5	3091520	H32619S

A distributor in Sweden has reported that a product was shipped with labelling in the wrong language. The same issue was encountered in Finland, Norway, and Denmark.
Without proper language labelling, users may not recognize warnings or misunderstand product handling and thus compromise device performance and/or patient or user safety.

As a precautionary measure, we are releasing the attached Field Safety Notice to alert customers and recall and/ or destroy the products concerned.
We kindly ask you to take the following actions:

- Please do not use or distribute the identified products. If you have distributed these products to your customers, it is essential that you inform them about the issue and advise them to stop use or distribution.
- Complete the attached reply form: review the information in this document, follow the appropriate actions outlined in section 3, and confirm your understanding and compliance with the outlined measures. Please return the Customer Reply Form to us within four weeks after receiving the FSN. In case you have distributed the products to your customers, please collect their responses and complete a single reply form with aggregated data.

We sincerely apologize for any inconvenience this may cause and appreciate your understanding and cooperation in this matter.

Best regards,

Ecolab Vigilance
On behalf of Laboratoires Anios

LABORATOIRES ANIOS, An Ecolab Company
Address: 1, rue de l'Espoir, 59260 Lezennes – France
Website : www.anios.com Email: info@anios.com

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Field Safety Notice (FSN)
ANIOSYME SYNERGY 5,
Missing local language label

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Medical device
1.	2. Commercial name(s)*
	Aniosyme Synergy 5
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	Cleaning of medical devices and instrumentation
1.	5. Device Model/Catalogue/part number(s)*

Product	SKU	Batch Numbers
Aniosyme Synergy 5	3091520	H32619S

1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	See above
1.	8. Associated devices
	N/A

2. µµ	
2.	1. Description of the product problem*
	A distributor in Sweden reported that some products were shipped with labelling in the wrong language. The same issue was confirmed for Finland, Norway, and Denmark.
2.	2. Hazard giving rise to the FSCA*
	Without proper language labelling, users may not recognize warnings or misunderstand product handling and thus compromise device performance and patient safety. Product delivered are compliant and no patients have been impacted nor any health risk reported.

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3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the END-USER*** ☒ Identify Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification / inspection ☒ Inform all users within your facility ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
	2. Action To Be Taken by the DISTRIBUTOR* ☒ Identify Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification / inspection ☒ Inform your end-customers ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	3. By when should the action be completed?	Immediately
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes Within 4 weeks after receipt of the FSN
3.	**5. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None All impacted products will be destroyed	

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4. General Information*		
4.	1. FSN Type*	New
4.	2. 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.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	Annex A: Customer reply form

	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.

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