1 rue de l'Espoir
59260 LEZENNES
France
Tel +33 3 20 67 67 67
Fax + 33 3 20 67 67 68
Email Vigilance@anios.com

To Healthcare Organisation Name
Address

URGENT
FIELD SAFETY NOTICE

Date: 0/11/22

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

Affected products:

Device Commercial Name	Packaging	Article Code
SURFA'SAFE PREMIUM	12x750ML	2419326*, 2419544, 2419544HD

**diffused foam form products*

Madam, Sir,

We have identified that you received products in the above table, and we are recalling all batches (Annex II) as they do not comply with our quality expectations. They may contain the opportunistic environmental microorganism Burkholderia Cepacia.

Burkholderia cepacia 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.

The products are available in a variety of packaging: foam sprays, diffused foam sprays (see indication in the above table) and dropping bottles. Depending on the indicated application of the products, the risks are different. When using a diffused foam form, the risk is higher for the at-risk population due to possible inhalation exposure. When using the product in a wiping action, the probability of the bacteria infecting the at-risk patient population is less important. Laboratory data indicates that in Surfa'Safe Premium the bacteria dies two and a half minutes after product use on surfaces.

Corrective actions to eliminate the contamination source are being implemented. We have introduced additional hygiene security protocols which means that all our medical devices manufactured and delivered from our Sainghin-en-Mélantois plant will have successfully passed the test protocols.

For precautionary reasons, we ask that you stop immediately using the recalled products that you may have in stock, as there is a risk they may be contaminated.

We ask you to isolate these products locally and to inform us about the quantity you have in stock by sending us the reply form (Annex I) to the following e-mail address: Vigilance@anios.com.

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Healthcare Organisation Name
Address

ANNEX I
CUSTOMER REPLY FORM

1. **Field Safety Notice (FSN)** FSN

Reference:

FSN_ANIOS_SSP_EN_EX EU_SWISS

FSN Date: November *22, 2019*

Affected products: ***Please refer to Annex II***

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 informed the supplier of the stock I have that is subject of the recall and needs to be returned

PERSON OF CONTACT FOR RETURN OF GOOD: _____

EMAIL OF CONTACT: _____

PHONE NUMBER OF CONTACT: _____

Device Commercial Name	Article Code	Batch N°	Packages Quantity (units)

☐ No affected devices are available for return

☐ Other Action (Define):

4. Return acknowledgement to sender

Email	Vigilance@anios.com
Postal Address	Laboratoires ANIOS Service qualité 1, rue de l'Espoir 59260 Lezennes - France
Fax	+33 3 20 67 67 68
Deadline for returning the customer reply form	05/12/2019

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 action

Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 05/12/2019 - the completed and signed reply form.

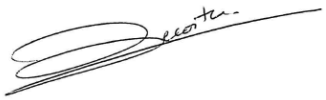
Your Anios representative will contact you to discuss the return of the recalled product you have in stock. We remain at your entire disposal for any question or assistance that you may need.

The undersigns confirm that this notice has been reported to the appropriate Regulatory Agency.

We would like to remind you of your obligation to report to your regional health agency any infection or serious incident associated with your care.

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.

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E:mail vigilance@anios.com

ANNEX II
AFFECTED PRODUCTS BATCHES

1. **Field Safety Notice (FSN)**

FSN Reference:

FSN_ANIOS_SSP_EN_EX EU_SWISS

FSN Date: *November 22, 2019*

Reply form: ***Please refer to Annex I***

Article name	**Article code**	**Batch number**
SURFA'SAFE PREMIUM 12X750ML	2419544	A08805S
		A11002S
		A11612S
		A15601S
		A16909S
		A18601S
		A24309S
		A24610S
		A29211S
		A31819S
		A32501S
		A34905S
		A35220S
		B02902S
		B07719S
		B12808S
		B14716S
		B16427S
		B20310S
		B21924S
		B23907S
		B26109S
		W35309S
	2419544HD	A31819S
		B00909S
		B04105S

		B19206S
		B20529S
SURFA'SAFE PREMIUM ROUGE 12X750M	2419326	A01024S
		B03721S