D.M.D

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: 07/11/19

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

Affected products:

Device Commercial Name	Packaging	Article Code
DENTASEPT SH PRO	12x750ML	2462326R8*
	1X5L	2462042R8
	1X750ML	2462892*
DISINFECTANT DETERGENT SPRAY	12x750ML	2654241HU
	1X5L	2654042HU
KIT FLACON	12x750ML	2514440*
KLINION DESINFECTANT	6X750ML	2518443
NORMOBIOT PS NF	12x750ML	2544241EZ
VAPOSEPT ZERO	1X5L	2763047
	6X750ML	2763382T1

**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, the bacteria, if present in the product, dies two and a half minutes after product use on surfaces (see in Annex III the test report conducted with SURFA'SAFE PREMIUM, equivalent product to the recalled ones).

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.

Customer n°: FSN_DMD_SSP_DISTRIBUTORS_EN_EX NON EU

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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 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.

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.
The proof of products' destruction could be requested to close the current action.

Your Anios representative will contact you to discuss the destruction 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*	Pierre-Marie Marcelet *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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Healthcare Organisation Name
Address

ANNEX I
CUSTOMER REPLY FORM

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

FSN Reference:
FSN_DMD_SSP_DISTRIBUTORS_EN_EX NON EU

FSN Date: November 7*, 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 *

D.M.D

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 to vigilance@anios.com)

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

☐ No affected devices are available for destruction

☐ Other Action (Define):

4. Return acknowledgement to sender

Email	Vigilance@anios.com
Postal Address	DMD 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 actions

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ANNEX II
AFFECTED PRODUCTS BATCHES

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

FSN_DMD_SSP_DISTRIBUTORS_EN_EX NON EU
FSN_DMD_SSP_DISTRIBUTORS_EN_EX EU

FSN Date: *November 7, 2019*

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

2. **Affected Products Batches**

Device Commercial Name	Packaging	Article code	Batch number
DENTASEPT SH PRO	12x750ML	2462326R8	A03613S
			A08210S
			A15803S
			A21202S
			A26023S
			A26803S
			A29211S
			A34106S
			B01524S
			B10629S
			B11318S
			B12312S
			W35411S
	1X5L	2462042R8	A03211S
			A12712S
			A16307S
			A21502S
			A28403S
			A30910S
			A31412S
			A34406S
			B00827S
			B10629S
			B12919S
			B13509S
			B17826S
			W30805S
			W35411S

D.M.D

Device Commercial Name	Packaging	Article code	Batch number
DENTASEPT SH PRO	1X750ML	2462892	A26023S
			B12312S
DISINFECTANT DETERGENT SPRAY	12x750ML	2654241HU	A11204S
			A17821S
			A31018S
			B04105S
			B15505S
			B19604S
	1X5L	2654042HU	A01711S
			A07909S
			A28403S
			B04105S
			B10629S
			B19206S
KIT FLACON	12x750ML	2514440	A04606S
			A14911S
			A23703S
			B05121S
			B13509S
			W35411S
KLINION DESINFECTANT	6X750ML	2518443	A02404S
			A06406S
			A07305S
			A11204S
			W31810S
			W33210S
			W34906S
NORMOBIOT PS NF	12x750ML	2544241EZ	A08702S
			A09917S
			B07927S
			B25428S
			W29306S
VAPOSEPT ZERO	1X5L	2763047	A23320S
			B07318S
	6X750ML	2763382T1	A04305S
			A07305S
			A09420S
			A17821S
			A21915S
			A33705S
			B10724S
			W34701S

Laboratoires ANIOS
Laboratoire de microbiologie

Numéros de demande : 38 515

Sainghin-en-Mélantois , on the October 31th 2019

Responsibles :

Dr LOEFFERT FREMIOT Sophie
PLUCHART Chrystèle

Study followed by :

LAURENT Meghan

PURPOSE OF THE STUDY :

Study of the survival of the bacteria *Burkholderia cepacia* contained in the disinfectant detergent SURFA'SAFE PREMIUM after application on two types of surface

In charge of the study :

Chrystèle PLUCHART
Microbiology Laboratory Manager

Sophie LOEFFERT FREMIOT
Microbiology Manager

This document has 5 numbered pages including 0 appendix

Study n°: 38515

Laboratoires ANIOS SAS
Adresse : Pavé du moulin – 59260 Lille-Hellemmes
Tél. +33 3 20 67 67 67 – Fax : + 33 3 20 67 67 68
SIREN : 823 326 061 – SIRET : 823 326 061 00020
VAT : FR71823326061 – Capital Social : 773 630 132 euros

PROTOCOL

The tests described below were carried out based on the standard NF EN 16615 (May 2015) "Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces, with mechanical action using wipes in the medical field (Phase 2 / Step 2) ".

Principle :

The disinfectant detergent SURFA'SAFE PREMIUM (lot B 274.24S) contaminated with the bacteria *Burkholderia cepacia* is applied on two types of surfaces according to the protocols described below.

Tested surfaces: Stainless steel and PVC.

Test areas are plotted 10/10 cm square on each surface

Six zones 10/10 cm are identified : 1, 2, 3, 4, 5, 6

- Protocol 1 : Two sprays of SURFA'SAFE PREMIUM (Batch B 274.24S) are applied to each test area of each surfaces (stainless steel / PVC) and wiping of each zone is carried out using a wipe (1 go- return).

- Protocol 2 : Two sprays of SURFA'SAFE PREMIUM (Batch B 274.24S) are applied to one wipe and then wiping of each test area of each surface (stainless steel / PVC) is carried out using this wipe (1 go- return).

Each operation is performed in duplicate.

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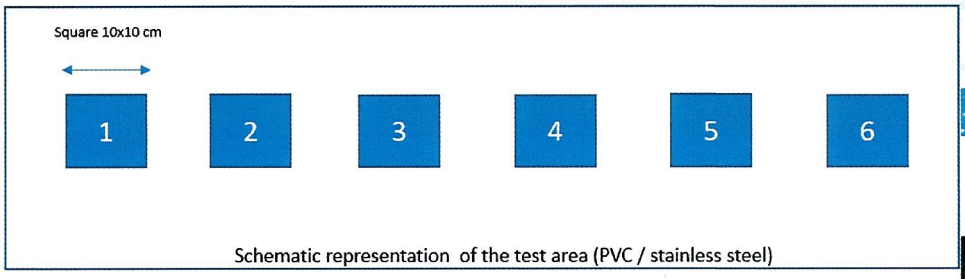
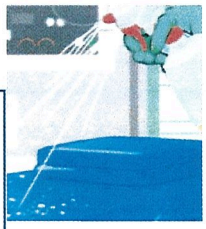
Below the diagram of the tests.

Protocol 1: On PVC and stainless-steal surface.



Schematic representation of the test area (PVC / stainless steel)



2 sprays on each square of 10x10 cm then wiping of each square with wipe

After the implementation of the protocol, a contact time is respected before proceeding to the sampling of residual germs on the surfaces.

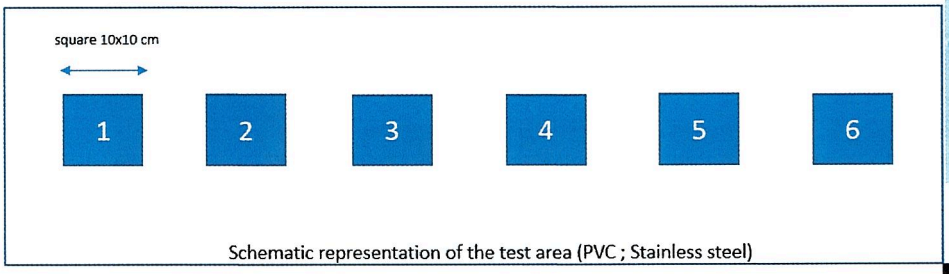
The experimental plan (zone/contact ime) is as follows :

Zone 1 : T0 : immediate
Zone 2 : Contact time of 1 min
Zone 3 : Contact time of 1 min 30
Zone 4 : Contact time of 2 min
Zone 5 : Contact time of 2 min 30
Zone 6 : Contact time of 3 min

The *Burkholderia cepacia* strain is recovered by applying a Count tact box for 10 seconds on each defined area.

The Petri dishes are then incubated for 48H at 30°C ± 1°C

Protocol 2: On PVC and stainless-steel surface.



Schematic representation of the test area (PVC ; Stainless steel)


2 sprays on the wipe then wiping each square with the wipe

After the implementation of the protocol, a contact time is respected before proceeding to the sampling of residual germs on the surfaces.

The experimental plan (zone/contact ime) is as follows :

Zone 1 : T0 : immediate
Zone 2 : Contact time of 1 min
Zone 3 : Contact time of 1 min 30
Zone 4 : Contact time of 2 min
Zone 5 : Contact time of 2 min 30
Zone 6 : Contact time of 3 min

The *Burkholderia cepacia* strain is recovered by applying a Count tact box for 10 seconds on each defined area.

The Petri dishes are then incubated for 48H at 30°C ± 1°C

Résults : Protocol 1

Surface PVC

Contact time	Zone 1 : T0 CFU/25 cm2	Zone 2: T1min CFU/25 cm2	Zone 3: T1min30 CFU/25 cm2	Zone 4: T2min CFU/25 cm2	Zone 5: T2min30 CFU/25 cm2	Zone 6: T3min CFU/25 cm2
Test Result	+	+	231	32	0	0
PVC	+	+	243	41	0	0
	+	+	217	25	0	0

Surface Stainless steal

Contact time	Zone 1 : T0 CFU/25 cm2	Zone 2: T1min CFU/25 cm2	Zone 3: T1min30 CFU/25 cm2	Zone 4: T2min CFU/25 cm2	Zone 5: T2min30 CFU/25 cm2	Zone 6: T3min CFU/25 cm2
Test Result	+	+	144	15	0	0
Inox	+	+	130	17	0	0
	+	+	127	19	0	0

Résults : Protocol 2

Surface PVC

Contact time	Zone 1 : T0 CFU/25 cm2	Zone 2: T1min CFU/25 cm2	Zone 3: T1min30 CFU/25 cm2	Zone 4: T2min CFU/25 cm2	Zone 5: T2min30 CFU/25 cm2	Zone 6: T3min CFU/25 cm2
Test Result	+	+	202	32	0	0
PVC	+	+	213	27	0	0
	+	+	227	39	0	0

Surface Stainless steal

Contact time	Zone 1 : T0 CFU/25 cm2	Zone 2: T1min CFU/25 cm2	Zone 3: T1min30 CFU/25 cm2	Zone 4: T2min CFU/25 cm2	Zone 5: T2min30 CFU/25 cm2	Zone 6: T3min CFU/25 cm2
Test Result	+	+	151	22	0	0
Inox	+	+	163	20	0	0
	+	+	140	17	0	0

Conclusion :

Regardless of the protocol and the surface, the results of the tests demonstrate that the *Burkholderia cepacia* strain contained in SURFA'SAFE PREMIUM (Batch B 274.24S) is no longer present after 2 minutes 30.