

1 rue de l'Espoir
59260 LEZENNES
France
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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
SURFA'SAFE PREMIUM contained in BACCIDE KIT PRO	12x750ML	2524326*
ECI MND PREMIUM	12x750ML	2722371
INSTRUNET SURFA'SAFE PREMIUM	12x750ML	2585544E2
SURFA'SAFE PREMIUM	12x750ML	2419326*, 2419326EZ*, 2419326HQ*, 2419544, 2419544BA, 2419544BR, 2419544D2, 2419544GA, 2419544HA, 2419544HD, 2419544S6, 2419544T4, 2419544UE, 2419544UO, 2419544UY, 2419544UZ
	16X500ML	2419105
	1X500ML	2419982
	1X50ML	2419874
	1X5L	2419922
	1X750ML	2419890, 2419890UY, 2419892, 2419892HQ
	4X5L	2419028, 2419028HR

**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

Customer n°:

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX EU

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 (Annex III).

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 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.

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 <i>Quality Manager</i>	Dr Monique Manche <i>Materiovigilance Contact Person</i>	Thomas Decoster <i>President</i>
		

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.

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

Healthcare Organisation Name
Address

ANNEX I CUSTOMER REPLY FORM

1. Field Safety Notice (FSN)

FSN Reference:

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX 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 *

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	<u>Vigilance@anios.com</u>
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 actions

1 rue de l'Espoir
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Tel +33 3 20 67 67 67
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E:mail vigilance@anios.com

ANNEX II AFFECTED PRODUCTS BATCHES

1. Field Safety Notice (FSN)

FSN Reference:

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX EU

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX NON 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
SURFA'SAFE PREMIUM contained in BACCIDE KIT PRO	12x750ML	2524326	A01510S
			A13802S
			A26023S
			A34406S
			B17802S
ECI MND PREMIUM	12x750ML	2722371	A03211S
			A04305S
			A13618S
			A15503S
			A16218S
			A17927S
			A19214S
			A23419S
			A26405S
			A29904S
			A33705S
			A34426S
			A36127S
			B01906S
			B02902S
			B04605S
			B05712S
			B08702S
			B10629S
			B13323S
			B14414S
			B16327S
			B17802S

Device Commercial Name	Packaging	Article code	Batch number
ECI MND PREMIUM	12x750ML	2722371	B19604S
			B23213S
			B26920S
			W33210S
			W34906S
INTRUNET SURFA SAFE PREMIUM	12x750ML	2585544E2	A00807S
			A01510S
			A02505S
			A04322S
			A05308S
			A06406S
			A08805S
			A10013S
			A10123S
			A10303S
			A11002S
			A11204S
			A13713S
			A15503S
			A16218S
			A17106S
			A18508S
			A21915S
			A22213S
			A22907S
			A23419S
			A23703S
			A26803S
			A28403S
			A29211S
			A29904S
			A31018S
			A31309S
			A32204S
			A34106S
			B00406S
			B01405S
			B02902S
			B03721S
			B04807S
			B05712S
			B06909S
			B07719S
			B08702S
			B10101S
			B11318S
			B12808S
			B14828S
			B17118S
			B17803S
			B19126S
			B20807S
			B23213S
			B23907S
			B24304S

Device Commercial Name	Packaging	Article code	Batch number
INTRUNET SURFA SAFE PREMIUM	12x750ML	2585544E2	W30805S
			W31810S
			W32023S
			W35411S
			W36314S
SURFA'SAFE PREMIUM	12x750ML	2419326	A01024S
			A01711S
			A02907S
			A04420S
			A05209S
			A05919S
			A08017S
			A08601S
			A10013S
			A11313S
			A11502S
			A11612S
			A13908S
			A14222S
			A15601S
			A15803S
			A16218S
			A16526S
			A16909S
			A17821S
			A18508S
			A19013S
			A20005S
			A21202S
			A22011S
			A26111S
			A26803S
			A27906S
			A28910S
			A29616S
			A31309S
			A32204S
			A33103S
			A34406S
			A35220S
			B00724S
			B01906S
			B03123S
			B03721S
			B05014S
			B06909S
			B07108S
			B07909S
			B08906S
			B09306S
			B11616S
			B13509S
			B14828S
			B15509S
			B17511S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419326	B17826S
			B19126S
			B20510S
			B23213S
			B23424S
			B24716S
			B25008S
			B26920S
			B27424S
			W31203S
			W32206S
			W33925S
			W34906S
			W35411S
		2419326EZ	A02505S
			A08017S
			A08601S
			A11313S
			A11502S
			A13908S
			A14911S
			A18508S
			A22011S
			A28227S
			A32320S
			A34106S
			B01906S
			B06323S
			B06909S
			B10724S
			B12606S
			B14414S
			B15509S
			B18102S
			B19718S
			B22416S
			B25008S
			W32206S
			W34809S
			W34906S
		2419326HQ	A05209S
			A08017S
			A13802S
			A18401S
			A21202S
			A28227S
			A28910S
			A31309S
			B00406S
			B02902S
			B04605S
			B06909S
			B08906S
			B14414S
			B19604S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419326HQ	B22416S
			B26920S
			W31203S
			W36314S
		2419544	A00408S
			A00807S
			A00928S
			A01024S
			A01510S
			A01711S
			A02404S
			A02505S
			A02907S
			A03613S
			A04322S
			A04420S
			A04606S
			A05209S
			A05308S
			A05720S
			A05919S
			A06406S
			A06816S
			A07424S
			A08017S
			A08210S
			A08601S
			A08805S
			A09420S
			A09520S
			A10013S
			A10123S
			A10303S
			A11002S
			A11204S
			A11313S
			A11612S
			A13202S
			A13417S
			A13618S
			A13713S
			A13802S
			A14222S
			A15211S
			A15503S
			A15601S
			A15703S
			A15803S
			A16909S
			A17106S
			A17404S
			A17613S
			A17715S
			A17821S
			A17927S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544	A18401S
			A18601S
			A19013S
			A19214S
			A19408S
			A20005S
			A20615S
			A21202S
			A21403S
			A21915S
			A22213S
			A22613S
			A22907S
			A23419S
			A23703S
			A24309S
			A24610S
			A26405S
			A26803S
			A26827S
			A27906S
			A28227S
			A28314S
			A28403S
			A28417S
			A28910S
			A29211S
			A29616S
			A29810S
			A29904S
			A31018S
			A31309S
			A31412S
			A31706S
			A31819S
			A32204S
			A32320S
			A32501S
			A32620S
			A32905S
			A33103S
			A34106S
			A34406S
			A34426S
			A34619S
			A34722S
			A34905S
			A35220S
			A35324S
			B00406S
			B00724S
			B00827S
			B01016S
			B01714S
			B01906S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544	B02902S
			B03123S
			B03721S
			B04605S
			B04807S
			B05014S
			B05301S
			B05507S
			B05712S
			B07318S
			B07719S
			B07909S
			B08016S
			B08702S
			B08906S
			B09306S
			B10101S
			B10521S
			B10724S
			B11208S
			B11318S
			B11616S
			B12312S
			B12606S
			B12808S
			B12919S
			B13323S
			B13509S
			B14716S
			B15102S
			B15509S
			B15701S
			B16427S
			B17118S
			B17511S
			B17803S
			B17826S
			B18102S
			B18604S
			B19032S
			B19126S
			B19916S
			B20310S
			B20529S
			B20807S
			B21121S
			B21228S
			B21403S
			B21924S
			B23907S
			B24118S
			B24304S
			B24716S
			B25008S
			B25326S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544	B25609S
			B26109S
			B27424S
			B28014S
			B28203S
			W30618S
			W30805S
			W31105S
			W31203S
			W31810S
			W32023S
			W32206S
			W32510S
			W32810S
			W33422S
			W33925S
			W34701S
			W34809S
			W34906S
			W35309S
			W35612S
			W36314S
		2419544BA	A04305S
			A08017S
			A13802S
			A17927S
			A21202S
		2419544BR	A22613S
			A10123S
			A14222S
			A16909S
			A17927S
			A31004S
			A31018S
			A31309S
			B04605S
			B07108S
			B08702S
			B10629S
			B20807S
			B23907S
			B25609S
		2419544D2	W31810S
			A05308S
			A06816S
			A11204S
			A12712S
			A13802S
			A20005S
			A22213S
			A26803S
			A28314S
			A31819S
			A32501S
			B10521S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544D2	B12312S
			W36314S
		2419544GA	A00807S
			A18601S
			B15505S
		2419544HA	A15503S
			A21202S
			B17802S
		2419544HD	A01024S
			A05209S
			A05308S
			A05919S
			A06406S
			A09420S
			A09520S
			A11204S
			A13618S
			A13802S
			A15803S
			A17927S
			A18601S
			A21915S
			A26111S
			A28403S
			A29616S
			A29810S
			A31819S
			A32501S
			A33705S
			A34619S
			B00406S
			B00827S
			B00909S
			B01405S
			B04105S
			B05712S
			B06909S
			B07909S
			B08702S
			B10724S
			B12919S
			B15509S
			B16327S
			B16906S
			B17802S
			B19126S
			B19206S
			B19604S
			B19916S
			B20529S
			B21924S
			B23424S
			B24716S
			B26109S
			W31203S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544HD	W33210S
			W35612S
		2419544S6	A05209S
			A12712S
			A15503S
			A19013S
			A22907S
			A29211S
			A31018S
			A34106S
			B04105S
			B04605S
			B10724S
			B11616S
			B15102S
			B16327S
			B19206S
			B22416S
			W31810S
			W33210S
			W34701S
		2419544T4	A05919S
			A26111S
			A28314S
			B01714S
			B19126S
		2419544UE	A01711S
			A06406S
			A19214S
			A22213S
			A34619S
			B01906S
			B02902S
			B04605S
			B07108S
			B10724S
			B15102S
			B19126S
			B21924S
			W31810S
			W36314S
		2419544UO	A04322S
			A13202S
			A19214S
			A23419S
			A34722S
			B07318S
			B15102S
			B19206S
			B23424S
			W30805S
			W32023S
		2419544UY	B11616S
			B23907S
			B24304S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544UY	B26920S
		2419544UZ	A02907S
			A05919S
			A08805S
			A11002S
			A15503S
			A15803S
			A18401S
			A21403S
			A22907S
			A26111S
			A28403S
			A28417S
			A31018S
			A33705S
			A34619S
			B00406S
			B00909S
			B03123S
			B04105S
			B08421S
			B08702S
			B10101S
			B10724S
			B12919S
			B16906S
			B18102S
			B20807S
			B28014S
			W33210S
			W33422S
			W33925S
			W36314S
	16X500ML	2419105	A00415
			A01911
			A03613S
			A05380S
			A06816S
			A08210S
			A11502S
			A12712S
			A14911S
			A15803S
			A16307S
			A16526S
			A17106S
			A17927S
			A18508S
			A20005S
			A21212S
			A21502S
			A23320S
			A23703S
			A26503S
			A28314S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	16X500ML	2419105	A31004S
			A31309S
			A33103S
			A34106S
			A35513S
			A36127S
			B00827S
			B01714S
			B02207S
			B03028S
			B05121S
			B06323S
			B07318S
			B08421S
			B10629S
			B12312S
			B13509S
			B14414S
			B15505S
			B16327S
			B19206S
			B19718S
			B20510S
			B21121S
			B23213S
			B25326S
			B25915S
			W31810S
			W32206S
			W33210S
			W34906S
			W35411S
	1X500ML	2419982	A00415
			A06816S
			A23320S
			B01714S
			B15505S
			B16327S
	1X50ML	2419874	B23213S
			A03613S
	1X5L	2419922	W34906S
			W31810S
	1X750ML	2419890	A01024S
			A01510S
			A01711S
			A02907S
			A06406S
			A08805S
			A10013S
			A10303S
			A11002S
			A13202S
			A13618S
			A14222S
			A15503S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	1X750ML	2419890	A18601S
			A21403S
			A22213S
			A24309S
			A26405S
			A27906S
			A28227S
			A28403S
			A31018S
			A33103S
			B03721S
			B07719S
			B09306S
			B12808S
			B14716S
			B15701S
			B18604S
			B21403S
			B25609S
			W30618S
			W30805S
			W31105S
			W33925S
			W34809S
		2419890UY	W34809S
		2419892	A00928S
			A01024S
			A01711S
			A02907S
			A05919S
			A08805S
			A15601S
			A26111S
			A31309S
			B06909S
			B08906S
			B17511S
			W30618S
			W30805S
			W31105S
			W33925S
			W34809S
		2419892HQ	A01711S
			W30618S
			W31203S
			W36314S
	4X5L	2419028	A03211S
			A10815S
			A16307S
			A19408S
			A21502S
			A30910S
			A34406S
			B02207S
			B09202S

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	4X5L	2419028	B10629S
			B12606S
			B17826S
			B19718S
			B24304S
			W31810S
		2419028HR	A23320S
			B02207S
			B24304S

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



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This document has 5 numbered pages including 0 appendix

Study n°: 38515

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

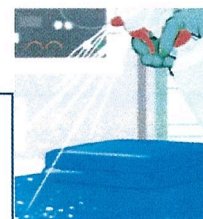
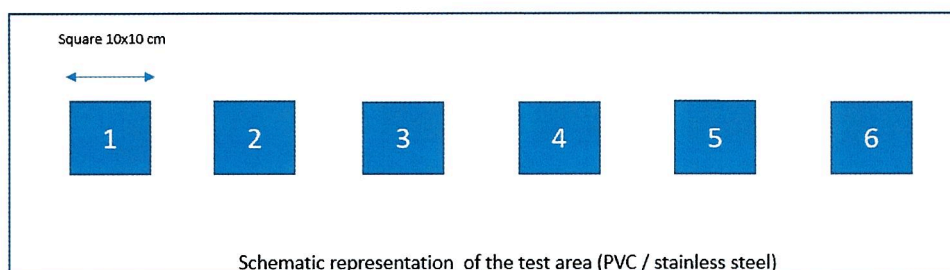
↳ Protocol 1 : Two sprays of SURFA'SAFE PREMIUM (Batch B 274.24S) are applied to each test area of each surfaces (stainless steel / PVC) and wiping of each zone is carried out using a wipe (1 go- return).

↳ 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.

Below the diagram of the tests.

Protocol 1: On PVC and stainless-steel surface.



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.

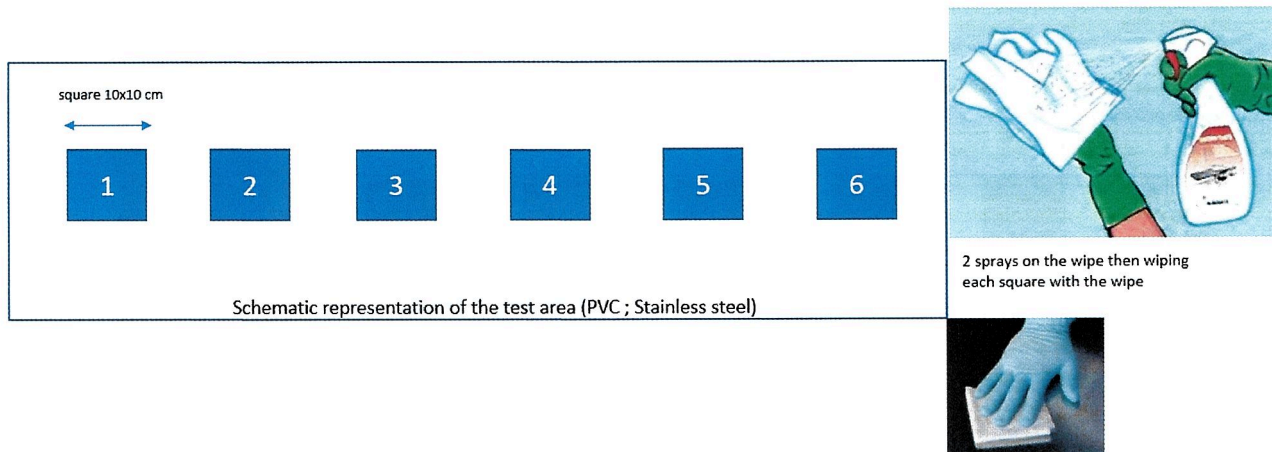
The experimental plan (zone/contact time) is as follows :

- 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.



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 time) 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 $30^{\circ}\text{C} \pm 1^{\circ}\text{C}$

Résultats : 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 steel

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

Résultats : 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 steel

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.