

Circular Informativa

N.º 176/CD/550.20.001

Data: 14/11/2019

Assunto: **Recolha voluntária de desinfetantes de dispositivos médicos**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373;
Fax: 21 111 7552; E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

O Infarmed, I.P foi informado pelo fabricante Laboratoires Anios e pela Autoridade Competente Francesa ANSM sobre a contaminação bacteriana verificada no processo de fabrico de desinfetantes de dispositivos médicos. Por este motivo, foram identificados os lotes de desinfetantes potencialmente contaminados, colocados no mercado pelo fabricante Laboratoires Anios bem como por outros fabricantes legais que subcontratam o fabrico ao primeiro.

Desta forma, os fabricantes estão a proceder à recolha voluntária dos lotes descritos em anexo dos seguintes dispositivos:

Fabricante: **Laboratoires Anios** (ver lotes - Anexo I)

Dispositivo médico	Modelo	Referência
BACCIDE KIT PRO	12x750ML	2524326
ECI MND PREMIUM	12x750ML	2722371
INTRUNET 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

Fabricante: **Laboratoires Anios** (ver lotes -Anexo II)

Dispositivo médico	Modelo	Referência
OPASTER ANIOS	4x5L	2504028C6, 2504028HA, 2504028OB, 2504028E2, 2643028BR, 2504028YS, 2504318UE, 2504028UO, 2504028G4, 2504028Z8, 2504028DL, 2504028JC, 25040282Q

Fabricante: **D.M.D.** (ver lotes - Anexo III)

Dispositivo médico	Modelo	Referência
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

Fabricante: **USF Healthcare** (ver lotes - Anexo IV)

Dispositivo médico	Modelo	Referência
UNISEPTA FOAM 2	12x750ML	2458241__L3, 2458241GM
	1X750ML	2458953
	2X5L	2458539__L3

As bactérias identificadas foram as *Burkholderia cepacia*, *Pseudomonas oryzihabitans* e *Delftia Acidovorans* que estão naturalmente presentes no meio ambiente, nomeadamente na água. Estas bactérias são “oportunistas”, o que significa que podem provocar uma infeção em pessoas imunodeprimidas, sendo o risco de infeção muito baixo para a população em geral.

O Infarmed não recebeu até à data nenhuma notificação de incidente relativamente a este problema.

A origem desta contaminação está associada à água da fábrica dos Laboratoires Anios localizada em Sainghin-en-Mélantois, tendo por este motivo sido suspensa a produção no sentido de se proceder à desinfeção do circuito de água. A produção só irá ser restabelecida após uma verificação da resolução deste problema pela Autoridade Competente Francesa (ANSM).

Perante o acima exposto, o Infarmed informa que:

- 1- Os distribuidores devem proceder à recolha do mercado dos desinfetantes listados contactando todos os clientes afetados.
- 2- Os utilizadores não devem, como medida de precaução, utilizar os desinfetantes acima listados e devem proceder à sua devolução ao respetivo distribuidor.
- 3- No caso de constrangimentos de disponibilidade de desinfetantes alternativos, os utilizadores deverão privilegiar a utilização destas alternativas em populações de risco (ex: imunodeprimidos, recém-nascidos, hemodialisados e doentes com mucoviscidose).

Quaisquer incidentes ou outros problemas relacionados com estes dispositivos médicos devem ser notificados à Unidade de Vigilância de Produtos de Saúde do Infarmed através dos contactos: tel.: +351 21 798 71 45; fax: +351 21 798 73 16; e-mail: dvps@infarmed.pt.

O Conselho Diretivo

Anexo I

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59260 LEZENNES France
Tel +33 3 20 67 67 67
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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
			A22613S
		2419544BR	A10123S
			A14222S
			A16909S
			A17927S
			A31004S
			A31018S
			A31309S
			B04605S
			B07108S
			B08702S
			B10629S
			B20807S
			B23907S
			B25609S
			W31810S
		2419544D2	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
		2419544UY	W32023S
			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
		2419892HQ	W34809S
			A01711S
			W30618S
			W31203S
	4X5L	2419028	W36314S
			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

Anexo II

**ANNEX II
AFFECTED PRODUCTS BATCHES**

Device commercial name	Packaging	Article code	Batch number
OPASTER'ANIOS	4X5L	250402800	A17117S
			A17819S
			A29105S
			A33405S
			B09205S
			B10707S
			B12012S
			B12705S
			B14507S
			B17003S
			B22506S
			B27801S
			U34216S
			W26313S
		2504028BF	A02612S
			W01915S
			W03912S
			W08116S
			W11018S
			W13912S
			W17208S
			W17711S
			W18406S
			W20511S
			W23316S
			W24909S
			W28407S
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			A27809S
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			A29012S

OPASTER'ANIOS

4X5L

2504028C6

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B28011S
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B28414S
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W03912S
W05108S
W07214S
W08116S
W09712S
W11018S
W13912S
W17208S
W17711S
W18406S
W20511S
W23316S
W24909S
W26313S
W28407S
W30006S
W30712S
W33114S

OPASTER'ANIOS

4X5L

2504028C6	W36013S
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	A26217S
	A27108S
	A28309S
	A32003S
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	B23109S
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	W36013S
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	A29204S

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			A35104S
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			A35405S
			A35508S
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			B10707S
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	1X5L	2504922	A05713S
			A10909S
			A35508S
			B09205S
			W13912S
			W17711S
			W36013S

Anexo III

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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

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
	6X750ML	2763382T1	B07318S
			A04305S
			A07305S
			A09420S
			A17821S
			A21915S
			A33705S
			B10724S
			W34701S

Anexo IV

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ANNEX II AFFECTED PRODUCTS BATCHES

1. Field Safety Notice (FSN) FSN

Reference:

FSN_USF_SSP_DISTRIBUTORS_EN_EX EU
 FSN_USF_SSP_DISTRIBUTEURS_EN_EX NON EU

FSN Date: November 8, 2019

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

2. Affected Products Batches

Device Commercial Name	Packaging	Article code	Batch number
UNISEPTA FOAM 2	12x750ML	2458241__L3	A03814S
			A08702S
			A15106S
			A21511S
			A26102S
			A31010S
			B00726S
			B07927S
			B10630S
			B16924S
			B19704S
			W34013S
		2458241GM	A03814S
			A15106S
			A26102S
			A33225S
			B07927S
			B16924S
			W34013S
	1X750ML	2458953	A21511S
			A26102S
			B10630S
	2X5L	2458539__L3	A03814S
			A09917S
			A13105S
			A19023S
			A21511S
			A26102S

Device Commercial Name	Packaging	Article code	Batch number
UNISEPTA FOAM 2	2X5L	2458539__L3	A31010S
			A33225S
			B00726S
			B07927S
			B10630S
			B13617S
			B16924S
			B19704S
			B25428S
			W32513S