



IDS Medical Systems (Singapore) Pte. Ltd.

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FIELD SAFETY NOTICE

19 November 2019

HSA

IDS REFERENCE:	FSCA-2019-013
MANUFACTURER REFERENCE:	-
SUBJECT: Product Recall for ANIOS SURFA'SAFE PREMIUM	
FOR THE ATTENTION OF: Chairman Medical Board (CMB), BME, Nursing and Medical staff using these devices in the various departments and the relevant Head of Departments.	
DEVICE:	SURFA'SAFE PREMIUM
PRODUCT CODE:	2419544
BATCH NO: (Supplied in Singapore)	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, 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, 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, B25609S, B26109S, B27424S, B28014S, B28203S, W30618S, W30805S, W31105S, W31203S, W31810S, W32023S, W32206S, W32510S, W32810S, W33422S, W33925S, W34701S, W34809S, W34906S, W35309S, W35612S
PROBLEM:	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.



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	<p>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 (Annex III).</p>
ACTION TO BE TAKEN:	<p>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.</p> <p>Please complete the acknowledgement form on the next page and we will arrange to collect the affected products back.</p>

We apologize for any inconvenience caused due to this notice. Meanwhile, should you require further clarification, please do not hesitate to contact the following personnel.

Mr. Michael Pan - [REDACTED]

Thank you.

With regards,
Bernard Wong
Regulatory
IDS Medical Systems (Singapore) Pte Ltd
Email: idsMEDSGPRegulatory@idsMED.com



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IDS Reference:	FSCA-2019-013
Manufacturer Reference:	NA
Device:	ANIOS SURFA'SAFE PREMIUM
Subject:	Product Recall for ANIOS SURFA'SAFE PREMIUM

I acknowledge receipt of this letter dated 19 November 2019.

Customer Name:	HSA		
Department:			
Address:			
Name:		Tel:	
Designation:			
Signature:		Company Stamp:	

Check the applicable boxes below:

<input type="checkbox"/>	I DO NOT have affected ANIOS SURFA'SAFE PREMIUM remaining. All have been used or discarded.
<input type="checkbox"/>	I DO have unused inventory of affected ANIOS SURFA'SAFE PREMIUM, which I will return for replacement / credit.

Item	Batch Number	Quantity to be returned	Please indicate if you prefer credit note or replacement.
ANIOS SURFA'SAFE PREMIUM			Credit / Exchange

**duplicate this list if you require more rows to input your data.*

Please email this acknowledgement to idsMEDSGPRegulatory@idsMED.com.

Thank you.