



IDS Medical Systems (Singapore) Pte. Ltd.

20 Science Park Road, Teletech Park

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FIELD SAFETY NOTICE

31 January 2019

PARKWAY HOSPITALS SINGAPORE PTE LTD-MNH
38 IRRAWADDY ROAD
SINGAPORE 329563

IDS REFERENCE:	FSCA-2019-002
MANUFACTURER REFERENCE:	-
SUBJECT: Product Recall for WIP'ANIOS PREMIUM, WIP'ANIOS EXCEL	
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:	WIP'ANIOS PREMIUM, WIP'ANIOS EXCEL
PRODUCT CODE:	2088655, 2446655
BATCH NO: (Supplied in Singapore)	WIP'ANIOS PREMIUM (2088655) A00219S, A05504S, A06105S, A18104S, A19123S, A19725S, U06705S, U08412S, U17605S, U21404S, U21512S, U25602S, U25702S, U32001S, U33419S, U36401S, W01618S, W04410S, W12905S, W14705S, W20304S, W20304S, W35214S WIP'ANIOS EXCEL (2446655) W04722S, W12423S, W25603S, W29906S, W34720S
PROBLEM:	A microbial contamination source has been identified and localized in an outsourced manufacturing process and has brought a potential bacterial contamination to some batches of manufactured wipes. In case of contamination triggered by contaminated wipes, immunocompromised patients would be at greater risk of infection. Globally, the risk assessment for potential health hazard linked to the use of those wipes results in low risk for the patient and the user. It takes into consideration the products' indication, the absence of any adverse event report linked to the use of the wipes, the probability of infection occurrence and the results of additional investigations (limited survival time if the bacteria on surfaces and sensitivity of this bacteria to antibiotics: piperacilline (PTZ) and ceftazidime (CZD).
ACTION TO BE TAKEN:	For precautionary reasons, we ask you not to use any longer any remaining units you may have in stock bearing the batch numbers documented in the enclosed appendix, as they may contain some contaminated wipes. Please quarantine the affected batches for exchange.



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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.

Ms Sharon Yeo - [REDACTED]

Mr Soo Wei Cheng - [REDACTED]

Thank you.

With regards,

Tan Qi Lun

Regulatory

IDS Medical Systems (Singapore) Pte Ltd

Email: idsMEDSGPRegulatory@idsMED.com



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IDS Reference:	FSCA-2019-002
Manufacturer Reference:	NA
Device:	WIP'ANIOS PREMIUM, WIP'ANIOS EXCEL
Subject:	Product Recall for WIP'ANIOS PREMIUM, WIP'ANIOS EXCEL

I acknowledge receipt of this letter dated 31 January 2019.

Customer Name:	PARKWAY HOSPITALS SINGAPORE PTE LTD-MNH		
Department:			
Address:	38 IRRAWADDY ROAD SINGAPORE 329563		
Name:		Tel:	
Designation:			
Signature:		Company Stamp:	

Check the applicable boxes below:

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

Item (WIP'ANIOS PREMIUM / WIP'ANIOS EXCEL)	Batch Number	Quantity to be returned

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

Please email this acknowledgement to idsMEDSGPRegulatory@idsMED.com.

If there is any discrepancy in the above list, please advise us of the changes.

Thank you.



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59260 Lille-Hellemmes
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web vigilance@anios.com

To IDS MEDICAL SYSTEMS (SINGAPORE)
PTE LTD.
CEO
TELETECH PARK, #01-23/25
117674 SINGAPORE SCIENCE PARK II
SINGAPORE

URGENT FIELD SAFETY NOTICE

Date: 22/01/19

Object:

- Batch recall
 Information and/or recommendations

Affected products:

Device Commercial Name	Article Code	Packaging
WIP'ANIOS PREMIUM	2088655BR /2088655C4 / 2088655C5	6 X 100 WIPES
WIP'ANIOS EXCEL	2446424C2 /2446424ZA	12X50 WIPES
	2446492GX	12X60 WIPES
	2446655C4 / 2446655C5 / 2446655CO / 2446655Y6	6 X 100 WIPES

Madam, Sir,

A microbial contamination source has been identified and localized in an outsourced manufacturing process and has brought a potential bacterial contamination to some batches of manufactured wipes.

In case of contamination triggered by contaminated wipes, immunocompromised patients would be at greater risk of infection. Globally, the risk assessment for potential health hazard linked to the use of those wipes results in low risk for the patient and the user. It takes into consideration the products' indication, the absence of any adverse event report linked to the use of the wipes, the probability of infection occurrence and the results of additional investigations (limited survival time of the bacteria on surfaces and sensitivity of this bacteria to antibiotics: piperacilline (PTZ) and ceftazidime (CZD).

Corrective actions to eliminate the contamination source have been implemented and are being closely monitored.

For precautionary reasons, we ask you not to use any longer any remaining units you may have in stock bearing the batch numbers documented in the enclosed appendix, as they may contain some contaminated wipes.

We would be grateful if you could acknowledge receipt of the present communication by returning at your earliest convenience - but no later than 28/02/2019 - the attached reply form duly completed and signed.




If applicable, the proof of product's destruction has to be provided to close the current action.

Your sales contact remains 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

<p>Isabelle Prévost <i>Quality Manager</i></p>	<p>Dr Monique Manche <i>Materiovigilance responsible</i></p>	<p>Bertrand Letartre <i>CEO</i></p>
		

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation 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.

APPENDIX 2

AFFECTED PRODUCTS

Medical device name	Model	Reference number	Lot/batch number
WIP'ANIOS EXCEL	12 packs of 50 wipes	2446424C2	A00324S
			A04420S
			A06805S
			A08122S
			A21502S
			A23602S
			A25015S
			A26503S
			A28107S
			W01716S
			W02615S
			W04204S
			W07004S
			W17911S
			W19303S
			W25811S
			W26321S
	2446424ZA	A00807S	
		A23602S	
	12 packs of 60 wipes	2446492GX	A12712S
			A20701S
			A26215S
			W33121S
	6 packs of 100 wipes	2446655C4	A02518S
			A02615S
			A03211S
			A04305S
A06805S			
A07305S			
A14911S			
A16210S			
A17404S			
A18712S			
A19311S			
A20108S			
A20409S			
A23320S			
A23602S			
A24126S			
A28107S			
W00513S			
W03015S			
W04204S			
W06116S			
W06823S			
W07917S			
W08310S			
W09318S			

APPENDIX 2

AFFECTED PRODUCTS

Medical device name	Model	Reference number	Lot/batch number		
			W13516S		
			W14205S		
			W15010S		
			W15111S		
			W16619S		
			W17823S		
			W20720S		
			W21215S		
			W23603S		
			W23804S		
			W24717S		
			W25104S		
			W25811S		
		2446655C5	A00807S		
			A02615S		
			A06805S		
			A16210S		
			A19311S		
			A28107S		
			W03015S		
			W04722S		
			W12423S		
			W25603S		
			W29906S		
			W34720S		
			W35612S		
		2446655CO	W03015S		
		2446655Y6	A24126S		
			A24712S		
			A24829S		
		WIP'ANIOS PREMIUM	6 packs of 100 wipes	2088655BR	W01618S
					W03821S
					W18418S
W26111S					
2088655C4	A00219S				
	A18104S				
	A19123S				
	U08405S				
	U11821S				
	U17703S				
	U21512S				
	U25702S				
	U32001S				
	W01618S				
W03821S					
W10912S					
W18418S					
W20304S					

APPENDIX 2

AFFECTED PRODUCTS

Medical device name	Model	Reference number	Lot/batch number
			W24313S
			W26111S
			W29209S
			W35214S
		2088655C5	A00219S
			A05504S
			A06105S
			A18104S
			A19123S
			A19725S
			U06705S
			U08405S
			U08412S
			U17605S
			U21404S
			U21512S
			U25602S
			U25702S
			U32001S
			U33419S
			U36401S
			W01618S
			W04410S
			W10104S
			W10912S
			W12905S
			W14705S
			W18418S
			W20304S
			W24313S
			W26111S
			W29209S
			W35214S