GAMA Healthcare Ltd.,
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Ref: CAPA-2021-07
MHRA Ref: 2021/005/005/601/530
26/07/2021

Clinell Universal Wipes – Urgent recall – **UPDATE**
REF CW200

Updates are highlighted in Bold

Updated Lot numbers UBV3032520A, UBV3032520B, UBV1032720A & UBV7032720A

Original Lot numbers UBV1033020A, UBV2033020A, UBV3033020A, UBV4033020A, UBV6032920A,

ISSUE

Recent, routine testing of **nine** Lots/batches of Universal Wipes, REF CW200 manufactured in one of our smaller factories has identified contamination with ***Burkholderia contaminans***.

B. contaminans is a Gram-negative bacilli, that belongs to Taxon K (group K) of the Burkholderia cepacia complex (Bcc) and is found widely in the natural environmental including soil and water.

Described as 'opportunistic pathogen' B. contaminans poses little medical risk to healthy individuals but can cause serious infections in those with compromised immune systems notably individuals with cystic fibrosis and chronic granulomatous disease.
Bcc is a known cause of infections in hospitalised patients, particularly those with weakened immune systems, spread by person to person contact or contact with contaminated surfaces.

Treatment of individual infections with Bcc present a challenge as it is often resistant to many of the more commonly used antimicrobials. Over the last couple of decades, outbreaks of Bcc infection have been linked to contaminated environments, devices, solutions and medications.
GAMA Healthcare are initiating an immediate recall of the batches identified whilst continuing the ongoing investigations.

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The originally identified five batches were manufactured in July 2020 and were distributed between 11th September and the end of December, 2020. **The updated batches were manufactured on three days June, 2020 and were distributed between 31st July, 2020 and 4th November, 2020.** If GAMA supplied you directly, you will receive a direct communication with specific dates, order numbers and Lot details to allow simpler product identification. If you were supplied through an NHS central system in the UK, your MDSO will have received this notice.

ACTION

Please identify and isolate any of this batch of wipes remaining in stock or issued within your organisation. The LOT number is printed in black on the top edge of the pack, above the expiry date. For cartons, the Lot number is printed on a label on the side of the box. Once isolated, please complete the attached form and return to GAMA as soon as possible but, in any case, no later than the **20th August, 2021**.

GAMA Healthcare would prefer for you to destroy any identified stock, but we can coordinate return and destruction if needed. A credit will be issued upon return of the attached Return Notice.

For any queries about this recall, please contact GAMA Regulatory Team;

Regulatory@gamahealthcare.com, or by calling GAMA by phone on +44 (0) 207 993 0030 and selecting the Regulatory option from the menu.

Graham Milward
Deputy Regulatory Affairs & Quality Assurance Director
GAMA Healthcare Ltd

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	CAPA-2021-07
FSN Date*	Original 21/05/2021 **– Update 04/08/2021**
Product/ Device name*	Clinell Universal Wipes - Pack of 200
Product Code(s)	CW200
Batch/Serial Number (s)	**UPDATE** **UBV303250A, UBV303250B, UBV1032720A & UBV7032720A** UBV6032920A UBV1033020A UBV2033020A UBV3033020A UBV4033020A

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the	Customer to complete or enter N/A

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	attention of all relevant users and executed.			
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):			
☐	I do not have any affected devices.	Customer to complete or enter N/A		
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query		
Print Name*		Customer print name here		
Signature*		Customer sign here		
Date*				

4. Return acknowledgement to sender	
Email	regulatory@gamahealthcare.com
Customer Helpline	+44 (0) 207 993 0030
Postal Address	GAMA Healthcare Ltd., The Maylands Building, Maylands Avenue, Hemel Hempstead Industrial Estate, Hemel Hempstead, Hertfordshire, HP2 7TG United Kingdom
Web Portal	www.gamahealthcare.com
Fax	N/A
Deadline for returning the customer reply form*	20th of August, 2021

Mandatory fields are marked with *

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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.