Clinell Universal 200 (CW200) Product Recall Notice

Dear Customer,

As a valued customer of GAMA Healthcare it was important that we inform you of a Product Recall Notice we have made against 5 batches of our Clinell Universal CW200 Wipes (CW200).

During the unprecedented global demand of COVID-19 our main factory producing CW200 was at full capacity which meant GAMA Healthcare had to use other facilities to maintain supply.

GAMA Quality Control, has identified an issue relating to 5 batches of product in one of our smaller production facility produced last year in July.

Through routine testing GAMA identified our Clinell Universal CW200 product had been contaminated with low level naturally occurring bacteria (Burkholderia Cepacia).

As a result of this contamination GAMA Healthcare stopped production immediately and instigated a product recall for the 5 batches of Clinell Universal CW200 products that had been affected by this issue.

Although, very unlikely, these products will still be available for RECALL due to the Corona Virus Pandemic but GAMA Healthcare is initiating an immediate recall of the batches identified.

BATCHES Include-

**UBV1033020A, UBV2033020A, UBV3033020A, UBV4033020A, UBV6032920A**

**ACTION**

If you do still have stock supplied from `September to November` GAMA Healthcare would ask that you 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 June 04, 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**](mailto:Regulatory@gamahealthcare.com)**, or by calling GAMA by phone on +44 (0) 207 993 0030 and selecting the Regulatory option from the menu.**

As a GAMA distributor, you may coordinate the recall and replace GAMA details as first contact in any of the bold text above, but must complete and return the Customer Reply Form attached.

GAMA Healthcare is investigating how the contamination entered the production process at this smaller factory at this time and also instigated a Decontamination or Deep Clean of the facility so manufacturing could return to normal as quickly as possible.

ALL other products manufactured in 2020 were produced to the highest quality. On-going testing has continued to demonstrate that only 5 batches or 127, 000 packs suffered this drop in quality in this production window.

For reference GAMA produces 12 Million packs per year of CW200 and this contamination affected 127,000 packs which constitutes 1% of annual product.

We continue to value your customer and appreciate times are still very hard with Corona Virus pandemic so will continue to support you in the normal GAMA way.

Chart, line chart

Description automatically generated

Graham Milward

Deputy Regulatory Affairs & Quality Assurance Director

GAMA Healthcare Ltd

**Customer Reply Form**

|  |  |
| --- | --- |
| 1. **Field Safety Notice (FSN) information** | |
| FSN Reference number\* | CAPA-2021-07 |
| FSN Date\* | 21/05/2021 |
| Product/ Device name\* | Clinell Universal Wipes - Pack of 200 |
| Product Code(s) | CW200 |
| Batch/Serial Number (s) | |  | | --- | | UBV6032920A | | UBV1033020A | | UBV2033020A | | UBV3033020A | | UBV4033020A | |

|  |  |
| --- | --- |
| 1. **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\* |  |

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| --- | --- | --- | --- | --- |
| 1. **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 attention of all relevant users and executed. | Customer to complete or enter N/A | | |
| 🞏 | 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 forreturn/ 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\* | |  | | |

|  |  |
| --- | --- |
| 1. **Return acknowledgement to sender** | |
| Email | [regulatory@gamahealthcare.com](mailto: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](http://www.gamahealthcare.com) |
| Fax | N/A |
| Deadline for returning the customer reply form\* | 4th June, 2021 |

Mandatory fields are marked with \*

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.