

To: Infection Prevention Lead

MHRA Field Safety Notice (FSN) Ref: 2021/005/005/601/530 – Clinell Universal Wipes (CW200)

The Medical Device Safety Officer (MDSO) at your Hospital Trust will be receiving a Field Safety Notice on Clinell Universal Wipe (CW200) advising that a low-level micro contamination occurred in 5 batches which were only produced in July 2020. During the unprecedented global demand of COVID-19 our main factory producing CW200 was at full capacity, which meant GAMA had to use other facilities to maintain supply. This contamination was an isolated issue at one smaller factory and ALL other products manufactured in 2020 were produced to the highest quality. For reference GAMA produces 12 Million packs per year of CW200 and this contamination affected 127,000 packs which constitutes 1% of annual product.

Frequently Asked Questions

Q. When did the product enter the supply chain?

A. The contaminated Clinell Universal CW200s first entered NHS Supply Chain on the 11th September extending to the end of December 2020.

Q. Did my hospital receive affected products?

A. It is likely your hospital received some of these batches in September 2020, but due to the volume of product used it is likely that the product has already been used. You will need to check batch codes of your existing stock to be sure. The following Lot numbers are contaminated:

(LOT UBV1033020A, UBV2033020A, UBV3033020A, UBV4033020A, UBV6032920A)

Q. What was the contamination?

A. *Burkholderia cepacia* complex (BCC), This complex is a group of closely related gram-negative bacilli found widely in the natural environment, including in soil and water.

Q. Was there any risk from this contamination?

A. *B. cepacia* 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.

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Q. How was the contamination identified and reported?

A. GAMA identified the quality issue during routine Quality Surveillance and reported it to the MHRA.

Q. What do I need to know?

A. All the affected customers have been notified directly about the contamination and advised on the appropriate action.

Q. Is there anything I should do or change?

A. No, unless you have been contacted directly on this issue (as mentioned above.) It is most important that you continue to clean and disinfect regularly as indicated by local trust protocols and in line with the training and instructions.

Customer Queries

If you or your colleagues require further information on the Field Safety Notice we will be happy to support.

Please contact your sales representative who will be happy to connect you with GAMA Regulatory colleagues.

Alternatively, you can contact the GAMA Regulatory team directly at Regulatory@gamahealthcare.com, or by calling GAMA by phone on +44 (0) 207 993 0030 and selecting the Regulatory option from the menu.

Yours faithfully,

GAMA Healthcare