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Investigation Findings and Stock Verification – ICN 3443

Dear NHS Patient Safety Team,

Regarding the investigation findings for the cutlery quality issue under ICN 3443, I am writing on behalf of Alliance Disposables to provide our formal response and stock check findings.

Firstly, we would like to thank you for bringing this issue to our attention. We fully understand your concerns regarding patient safety, and we respect the thorough due diligence you must undertake to ensure the integrity of the products supplied to the NHS estate. We offer our sincere apologies for this issue, specifically the reported presence of small metallic remnants between the tines of a number of forks, and for the resulting impact and disruption this may have caused.

Following the notification of the reported issue, we immediately initiated a comprehensive investigation to verify the quality of our inventories. We have checked the stock of this line currently held at our Crewe National Distribution Centre (NDC), which supplies NHS Supply Chain stock route lines. We are pleased to confirm that we found no examples or boxes containing similar issues within our own inventory. Furthermore, Alliance Disposables has no historical record of any similar quality issues. We regularly sell very large quantities of this and other Steelite-Utopia cutlery ranges without issue, and we believe the supplier's confidence in this product is fully justified based on our own extensive, trouble free commercial experience supplying the range.

As part of our joint investigation, our upstream supplier, Steelite-Utopia, has also undertaken extensive stock checks. They checked the stock held at their Chesterfield distribution centre, conducting spot checks across several thousand pieces of UK held stock, and confirmed that they did not identify the issue there either. Steelite-Utopia supplies large volumes of this product annually across the UK into high-volume healthcare, hospitality, and catering environments. A review of their Non-Conformance Report records dating back to 2018 identified no other reported incidents of this nature. They believe this occurrence represents an isolated manufacturing quality inspection failure, rather than a defect affecting a specific production batch. The matter has been formally raised with the manufacturer by Steelite-Utopia, and quality-control procedures have been reinforced to minimise any risk of recurrence.

To support end users and provide further assurance, we have detailed below the relevant cleaning and preparation instructions provided to us by Steelite-Utopia. These standard



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procedures should be followed before the cutlery is first put into service to ensure any loose manufacturing or handling residue is thoroughly removed:

- **Before First Use:** All cutlery must be thoroughly washed before it is first put into service. This is particularly important for new cutlery and ensures that any loose residue or material associated with the manufacturing, finishing, packing, or handling processes is removed before use.
- **Commercial Dishwashing:** The cutlery is suitable for cleaning in a commercial dishwasher. Prior to washing, any visible debris should be removed, and the cutlery should be washed using a normal dishwasher cycle and an appropriate commercial detergent, in accordance with the dishwasher and detergent manufacturers' instructions.
- **Loading:** For effective cleaning, cutlery should not be tightly packed within dishwasher baskets, allowing adequate water flow around each individual piece.
- **Drying and Inspection:** Following the completion of the wash cycle, the cutlery should be removed promptly, allowed to dry thoroughly, and visually inspected before being placed into service.

By following this standard procedure, appropriate and effective controls will be in place to ensure that any loose manufacturing or handling residue is removed before the product reaches the intended user.

Given that both our stock checks at Crewe NDC and Steelite-Utopia's inspections at their Chesterfield distribution centre yielded no further examples of this issue, we are confident that there is no batch-specific or general quality defect. We hope that this formal written confirmation provides the necessary assurance to enable you to update ICN 3443 and allow the release of the quarantined stock in the NHSSC regional distribution centres.

Should you require any further information, please do not hesitate to contact us.

Yours sincerely,
Carole Halliwell

Commercial Manager
Alliance Disposables Ltd



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