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CooperSurgical®

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February 15, 2023

CooperSurgical Reference: 1216677-2-12-2023-002-R
Media Recall: Global Total LP single step medium, 60mL
P/N: H5GT-060
Lot: 221118-010694

Dear Sir/Madam

CooperSurgical received four complaints (2023-01-0000226, -0000227, -0000228, & -0000229) on 11-Jan-2023 from a single customer alleging that one bottle of global total LP, 60 ml medium (H5GT-060) did not appear to contain protein, which is meant to be present in this medium. The discrepancy does not meet the product release specifications.

CooperSurgical will notify affected consignees via certified mail with confirmed delivery receipt, via email through provided addresses on purchase, and through marketing team direct communication. The notices distributed through these delivery techniques will identify the affected products and detail the necessary actions to be taken by customers who have received affected products.

A total of 190 bottles of the affected products were distributed globally. CooperSurgical determined that the affected product was distributed to 4 consignees in Germany.

CooperSurgical has initiated CM-008-2023 to determine root cause and implement a Corrective Action Plan (CAP) to address the root cause and prevent recurrence. Upon completion of all recall activities, CooperSurgical will formally submit a closure report. Please find attached the FSCA Report Form, list of affected consignees, and our HHE used for Risk Evaluation.

Sincerely,

Sr. Post Market Surveillance Manager