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8/12/2022

Medical Device Recall:

Humidifier bottle and syringe filter kit (6-count of each) for the BT37 Mark I Benchtop Incubator (AY102295)

Humidifier bottle and syringe filter kit (6-count of each) for the BT37 Mark II Benchtop Incubator (AY200246)

Lots: Appendix A

Dear Sir/Madam

CooperSurgical has sent a recall notification to all affected customers. The products are being recalled due to a repackaging procedure handled by CooperSurgical where the smaller syringe filter box was placed inside the larger humidifier bottle box. It was determined that there is the potential for sterile barrier damage during transport of product. CooperSurgical wishes to outline directly that this repackaging was taken by CooperSurgical and not by Planer Limited (the device legal manufacturer).

CooperSurgical has notified affected consignees via certified mail with confirmed delivery receipt, sent on 8-12-2022. The letter will identify the affected product and detail the necessary actions to be taken by customers who have received affected products. The letter will ask customers to contact CooperSurgical if they have any questions regarding the recall. At CooperSurgical's expense arrangements will be made to return affected unexpired product to CSI for credit.

A total of 5,182 kits are considered affected and distributed globally between June 27, 2019, and December 9, 2021. CooperSurgical determined that affected product was distributed to 2 consignees within Estonia.

CooperSurgical has initiate CAPA 773 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. Copies of the Health Hazard Evaluation and completed 806 Summary Report are enclosed.

Sincerely,
Daniel Huer

Daniel Huer

Manager of Risk Management

Appendix A – Potentially Affected Product Lots	
Lot Number	
AY102295	AY200246
05593V291121	18-1265
18-1192	18-1268
1812-68	18-1268 / G004639
18-1268	G004637
G000575	G004638
G003811	G004639
G003893	
G004517	
G004874	
G005109	
G005476	
G005723	
E160415	