

Urgent Field Safety Notice

Affected product: ART-1023 Quinn's Advantage Medium with Hepes

Type of action: Recall

Date: 2016-Nov-14

Attention: ART-1023 Customer

Affected Device

Quinn's Advantage Medium with Hepes

Product Code: ART-1023

Lot number: 16280126

Description of the problem

ORIGIO a/s has received two complaints regarding what appear to be particles, objects or growth in two bottles of the media. The media showed evidence of particulate matter, cloudiness, and was mis-colored.

It is highly important for ORIGIO a/s to eliminate the risk of microbial contamination. And due to this the ART-1023, Lot number 16280126 is recalled from the market. The affected lot number has been on the market from July, 2016; the expiry date is 2017-07-14.

Advice on action to be taken by the user

For the sake of good order we ask you kindly to confirm, with your signature on attached confirmation letter, that you will arrange the return of any of the affected products you may have on your inventory, and are not used.

Please contact your distributor/subsidiary to arrange for the return.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

ORIGIO a/s sincerely apologizes for any inconvenience caused to your clinic.

Best regards

Tove Kjær, Director Corporate Regulatory Affairs
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The undersign confirms that this notice has been notified the appropriate Regulatory Agency