



## Field Safety Notice

12 May 2017

Notification Number: CN-52554053

The purpose of this Field Safety Notice is to inform you of an issue impacting product(s) purchased by your company. A copy of this letter should be forwarded immediately to the personnel in your organization that utilize this product.

### Affected Product(s)

Item No.	Item Description	Lot / Batch
TT-10x5mL-B	BIOSCOT Monoclonal Control Reagent	N/A

### Description of the Issue

BIOSCOT Monoclonal Control Reagent is incorrectly classified as a non-Annex II “self-declared” IVD product under 98/79/EC Directive. This product will be re-classified and certified as an Annex II List A product.

### Reason for the Notification

This notification is to alert users that the current product is incorrectly classified under the 98/79/EC Directive and that Millipore (UK) Ltd. will be correcting this by certifying the product under the correct classification. There are no safety or performance issues associated with this notification. This notification is for information only.

### Corrective Action

We will be re-certifying this product as an Annex-II List A reagent. Once recertified the labelling and IFU will be updated to reflect the new classification. We anticipate approval of the new classification by the end of the year.

### Required/Recommended Action

Please immediately examine your inventory to determine if you have any remaining impacted product and forward a copy of this letter to the personnel in your organization that utilize this product and/or need to be made aware of this issue. Please complete the attached confirmation of receipt form and return to local contact indicated below.

Merck KGaA, Darmstadt, Germany  
Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt, Germany  
Phone +49 6151 72-0

EMD Millipore Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
290 Concord Road  
Billerica, MA 01821, U.S.A.  
Phone +1 (781) 533-6000

Sigma-Aldrich Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
3050 Spruce Street  
St. Louis, MO 63103 U.S.A.  
Phone +1 (800) 521-8956 (314) 771-5765

In addition, if you may have further distributed this product, please identify your customers and notify them at once of this issue. Your notification to customers should include a copy of this notification and Attachment 1.

## Attachments

### Attachment 1: Confirmation of Receipt of Notification

This notification has been evaluated and approved by representatives from Quality and Product Management.

If you would like more information regarding this notification, please contact Colette McGregor at [colette.mcgregor@merckgroup.com](mailto:colette.mcgregor@merckgroup.com)

We apologize for any inconvenience that this issue may cause you. Thank you for your loyal business.

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**Attachment 1**

**CONFIRMATION OF RECEIPT OF NOTIFICATION**

BIOSCOT Monoclonal Control Reagent (Catalogue #: TT-10x5mL-B)

Customer Notification ID #: CN-52554053

Company Name:

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I/We confirm receipt of the above-mentioned notification.

Name (Block capitals):

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Position:

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Email address (for follow-up contact):

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Signature:

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Date:

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**Please return to:**

Colette McGregor ([colette.mcgregor@merckgroup.com](mailto:colette.mcgregor@merckgroup.com))

Millipore U.K. Ltd.,  
2 Fleming Road,  
Kirkton Campus  
Livingston, EH54 7BN  
United Kingdom

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