



Täby 2023-06-26

## URGENT: FIELD SAFETY NOTICE

### Bioplate I, Bioplate II and Microtrays

FSCA reports: 6.6.2-2023-50286, 6.6.2-2023-50333 och 6.6.2-2023-50343

**All lots on the market and with an expiry date equal to or later than 01/2020.**

#### **Dear customers;**

We hereby inform you that the products mentioned have been delivered without a valid CE certificate and are therefore being recalled from the market.

Nothing in the products' design, production methods or materials have been changed. These are well-established products that have been available on the market for several decades. The intended field of use for these products remains unaltered. Please see attached statement från the contracted manufacturer *Information regarding Bioplate I, Bioplate II and Microtrays*.

#### **Products involved:**

LD9002	Bioplate I 1-10
LD9006	Bioplate II 1-10
9021	Microtrays Cyt 60

#### **Problem description**

There has been a mistake in renewing the CE certificates for the above-mentioned products. The valid certificate expired on 2020-01-16.

#### **Actions taken by Nordic Biolabs AB:**

- Reports have been sent to appropriate Regulatory Agencies in Sweden as well as in other European countries to which deliveries have taken place.
- Recalls of the products have been made and the products are discontinued for sale.

#### **Actions to be taken by the recipient of this communication:**

- Immediately stop the sale of current products.
- Recall of the products
- Provide Nordic Biolabs with information about the total amount of products in own stock and at customers. See attached Information regarding Bioplate I, Bioplate II and Microtrays.



#### **Nordic Biolabs AB**

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Box 7293  
SE-187 14 Täby  
Sweden

Adress  
Ritarslingan 16  
SE-187 66 Täby  
Arninge

Telefon vxl  
08-630 85 00  
Ordertelefon  
08-630 85 10

Org nr.  
556443-6789

Tel internat.  
+46 8 630 85 00

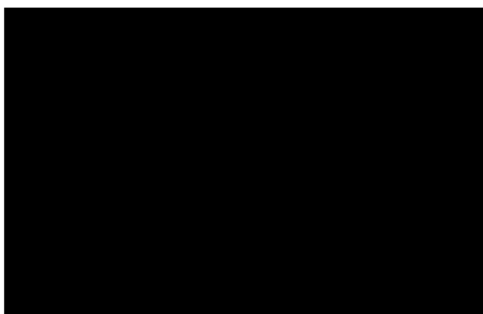
Bankgiro  
5784-6420

E-mail  
info@nordicbiolabs.se  
Web  
www.nordicbiolabs.se

Nordic Biolabs has informed the appropriate Regulatory Agencies of these actions and constantly renews its commitment to provide safe and quality products.

We apologize for any inconvenience this problem may cause to your organization, and please don't hesitate to contact Hajer Alm for any further request or need for clarification – [hajer.alm@nordicbiolabs.se](mailto:hajer.alm@nordicbiolabs.se) or +46 70 379 25 80.

Best regards,



**Attachments:**

Attachment 1  
Attachment 2

Attachment 1 to Urgent Field Safety Notice  
Information regarding Bioplate I, Bioplate II and Microtrays



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**ATTACHMENT 1**

to

**URGENT: FIELD SAFETY NOTICE****Bioplate I, Bioplate II and Microtrays**

FSCA reports: 6.6.2-2023-50286, 6.6.2-2023-50333 och 6.6.2-2023-50343

**All lots on the market and with an expiry date equal to or later than 01/2020.****Response Required**

**Return the completed and signed form to [hajer.alm@nordicbiolabs.se](mailto:hajer.alm@nordicbiolabs.se) as soon as possible and no later than three working days from the receipt of FIELD SAFETY NOTICE communication.**

***We require you to provide following information by ticking applicable box only:***

We do not have any of the involved products in our possession	<input type="checkbox"/>
We do have units of the involved products in our possession and we have blocked them. <i>Please specify item number, number of packages and batch number below.</i>	<input type="checkbox"/>

***Optional, please provide any relevant additional information below:***

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By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Organization name:	
Name:	
Job Title:	
Contact e-mail address:	
Contact telephone number:	
Signature:	
Date:	