

17.11.2020

Correction: urgent safety information (reply required, see page 2)

Product / batch: Serazym® Bovine Serum Albumin (BSA) sensitive (E-108)
14-05-19 and #15-04-20

Subject: Incorrect labeling of products; no influence on product functionality

Dear Sirs and Madames,

According to our records, you have received the product **Serazym® Bovine Serum Albumin (BSA) sensitive (E-108)** as a user.

We would like to inform you about a labeling error, which has no effect on the product functionality of the above mentioned product. By accident, the product was labeled as IVD / CE, which is incorrect.

The test processing and the performance data of the product are not influenced in any way. Due to legal reasons the test kits concerned **may no longer be used and remaining stocks must be returned to us.**

We ask you to confirm the receipt of this security information by email (info@seramun.com) or by fax (+49 33767 791 – 99) by 27.11.2020. You will find the reply document on page 2 of this letter.

From the next batch onwards, this incorrect labeling no longer occurs.

As part of the vigilance, Seramun Diagnostica GmbH reports this safety information as the manufacturer to the German national authority (BfArM).

If you have any questions about this measure, please feel free to contact us via email (info@seramun.com or Swantje.voelkner@seramun.com) or by telephone (+49 33767 791-10 or +49 33767 791-38).

We apologize very much for this mistake and the inconvenience this might have caused you.

Best regards



Swantje Völkner
safety officer
for medical devices

Seramun
Diagnostica GmbH
Spreenhagener Str. 1
15754 Heidesee
E-Mail: info@seramun.com
Tel.: +49 33767 791 10
Fax: +49 33767 791 99



Peter Lobeda
Managing Director

Reply

**for users - urgent safety information regarding incorrect labeling of product:
Serazym® Bovine Serum Albumin (BSA) sensitive (E-108)**

Please fill out and return to info@seramun.com or fax +49 33767 791 - 99 by **27.11.2020**

We hereby confirm, that we have read and taken note of the safety information including the recommended measures.

yes no

We hereby confirm, that we passed on the safety information including the recommended measures to all relevant employees and departments in the company.

yes no

There are (please enter number) _____ test kits in the warehouse (opened and unopened)

name: _____

position: _____

company: _____

street: _____

postcode/ town: _____

date / signature: _____

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subject: product recall

Seramun Diagnostica GmbH hereby blocks the use / transfer of the product with immediate effect

designation

batch-no.:

number of quantity delivered:.....

delivery date:

and asks for immediate return of the already opened or unopened products of the above-mentioned items that have been declared as "unfree" to the following address:

Seramun Diagnostica GmbH
Spreenhagener Str. 1
15754 Heidesee
GERMANY

If you have any questions, please contact us at

Tel. +49 33767- 791 10
Fax +49 33767- 791 99
E-Mail info@seramun.com

Best regards
Seramun Diagnostica GmbH

Peter Lobeda
Managing director