

2022-02-01

## Urgent Field Safety Notice

Sartorius Minisart NML 16534-----Q

FSCA-2022-01-28

Recall

### **Details on affected devices:**

We delivered one or more packaging units of Sartorius Minisart NML 16534-----Q with lot number 211486103 to you.

### **Description of the problem:**

We identified a quality issue for which a risk for patients cannot be completely excluded at the current state.

Precautionary we, therefore, ask you to return your stock of the product mentioned above to us. We will replace it free of charge.

### **Advice on action to be taken by the user:**

- Identify and quarantine the device and complete the form attached
- The affected products shall be returned to Sartorius Stedim Biotech GmbH
- Send back the confirmation form to Sartorius Stedim Biotech, please include [claimsreturns\\_opm\\_go@sartorius.com](mailto:claimsreturns_opm_go@sartorius.com) in the mailing list for organization of the product transport

### **Transmission of this Field Safety Notice:**

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

Please transfer this notice to all customers on which this action has an impact.

Sartorius Stedim Biotech GmbH  
August-Spindler-Straße 11  
37079 Göttingen, Germany  
Phone +49 551 308 0  
Fax +49 551 308 3289  
[www.sartorius.com](http://www.sartorius.com)

Registered Office:  
Göttingen  
Local Court of Registration:  
Amtsgericht Göttingen  
HRB No. 200266

Managing Directors:  
Becker, Uwe;  
Berendsen, Bettina

Chairman of the Supervisory  
Board:  
Dr. Joachim Kreuzburg

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

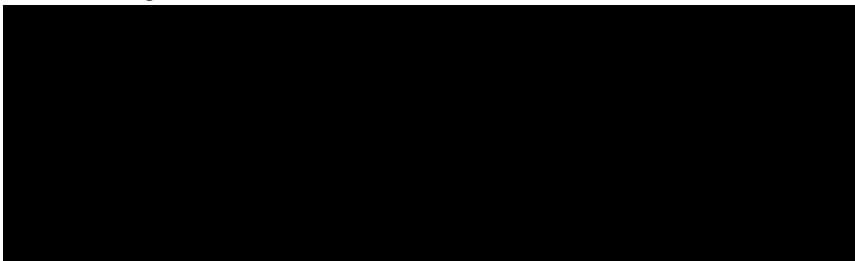
**Contact reference person:**

Rothhaar, Michael  
Sartorius Stedim Biotech GmbH  
Göttingen  
mobile: +49 170 7612396  
e-mail: michael.rothhaar@sartorius.com

The undersigned confirm that this notice has been reported to the appropriate regulatory agency.

We apologize for any inconvenience this may cause.

Best regards  
Sartorius Stedim Biotech GmbH  
Göttingen



Sartorius hereby expressly declares that this letter does not and shall not be deemed to constitute any acknowledgement, concession or admission that Sartorius and/or its Affiliates or Suppliers have breached or violated any law, rule, contract or regulation, or an acknowledgement that you or your affiliates, customers, or any other third party may have any claims against Sartorius and/or its Affiliates relative to this subject matter or any that could have been asserted pursuant to these details.

## Field Safety Corrective Action REPLY

**Please complete and return this record 22-02-07 by to**  
 Sartorius Stedim Biotech GmbH  
 August-Spindler-Straße 11  
 37079 Göttingen  
 Vigilance-SSB@Sartorius.com

Please enter below the quantity of packages and the material and lot numbers that you have in stock and that were quarantined following this notice:

Material Number	Lot Number	In Stock?	Quantity of Packages in Stock?	Quantity of Products Already Used
16534----- -----Q	211486103	<input type="checkbox"/> Yes <input type="checkbox"/> No		

The above Field Action has been carried out and the data given above are correct to the best of our knowledge. We have sent back all affected parts on stock.

Objective evidence about the execution of the Field Action is available on demand.

Signature and Date: \_\_\_\_\_  
 Name and Position |  
 Title: \_\_\_\_\_  
 Company: \_\_\_\_\_  
 \_\_\_\_\_