

Sartorius Stedim Biotech GmbH, 37070 Göttingen

To whom it may concern

August 3, 2023

**Urgent FIELD SAFETY NOTICE for Sartorius Minisart® HY | SRP Syringe**

Dear Valued Customer,

With this letter we would like to inform you of a possibly unclear description in the manual of Minisart® NML | HY | SRP Medical Device Syringe Filters for the following products:

| Material number | Description  |
|-----------------|--|
| 16596-----HYK   | Minisart HY, hydrophobic PTFE, 0.2 µm, 26mm, sterile, 50 pack      |
| 16596-----HYQ   | Minisart HY, hydrophobic PTFE, 0.2 µm, 26mm, non-sterile, 50 pack  |
| 16599-----HYQ   | Minisart HY, hydrophobic PTFE, 0.2 µm, 26mm, non-sterile, 500 pack |
| 16596-----ZSK   | Minisart HY, hydrophobic PTFE, 0.2 µm, 26mm, sterile, 50 pack      |
| 17575-----ACK   | Minisart SRP, hydrophobic PTFE, 0.2 µm, 25mm, sterile, 50 pack     |
| 17575-----ZSK   | Minisart SRP, hydrophobic PTFE, 0.2 µm, 25mm, sterile, 50 pack     |

The current description in the manual indicates several possible applications. This applies to all Minisart® HY | SRP syringe filters listed above, regardless of the manufacturing date and batch.

Please be informed that sterile filtration capabilities of oily solutions and liquids are depending on the solution properties. Usage of the above-mentioned filters for filtration of oily liquids may not result in a sterile filtrate in each setting. A non-sterile filtrate may possibly lead to an infection of the patient due to bacteria or other microorganisms.

**Please be advised that the sterile filtration capabilities in your specific application for oily solutions and liquids must be tested and validated by the user according to the needs of the specific application.**

We confirm that all relevant authorities have been notified.

We thank you for your trust and continued use of Sartorius products. If you have any questions, please contact [labfiltrationpm@sartorius.com](mailto:labfiltrationpm@sartorius.com).

Kind Regards

Adam Green  
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LPS Reagents & Consumables

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**Field Safety Notice  
REPLY**

Please fill out and return this record by **DATE (2 weeks after sending)** to  
labfiltrationpm@sartorius.com

Please confirm the following, if applicable:

- ☐ **I am NOT using this filter for sterile filtration of oily liquids**
- ☐ **I am using the filters for sterile filtration of oily liquids.**  
I acknowledge the need to test and validate the sterile filtration capabilities in my specific application for oily solutions and liquids.

If applicable, please enter below the quantity of packages and the material and lot numbers that you have in stock:

| Material Number | Lot Number | Quantity of Packages in Stock? |
|-----------------|------------|--------------------------------|
|                 |            |                                |
|                 |            |                                |
|                 |            |                                |
|                 |            |                                |
|                 |            |                                |

The above Field Safety Notice has been received and the data given above are correct to the best of our knowledge.

For Distributors: We have informed all affected customers.

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