

19. January 2021

Quality notification for Minisart® NML / Ophthalmart

Dear Customer,

Details on affected filters:

We delivered one or more packaging units of syringe filter Minisart® NML / Ophthalmart to you (see list of affected article numbers and lots attached).

Description of the problem:

We identified syringe filters (Minisart® NML / Ophthalmart) that may release fibers and particles (subvisible/visible) into the filtrate.

Advise on action to be taken by the user:

- Please inform us, how many filters you have on stock and how many have already been used by completing the attached form.
- Please identify and return all potentially affected filters according to the list attached. We will inform you as soon as possible on a lot basis, whether your lot(s) are indeed affected.
- If you have inventory of said filters, please complete the attached form and contact Claims Returns (CS-GoeSLI-complaints@Sartorius.com) for details on product return.

Transmission of this communication:

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 filters have been transferred.

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Dr. Joachim Kreuzburg

We apologize for the related inconvenience.

Best regards

Sartorius Stedim Biotech GmbH
Head of Operations Separation
Technologies



Dr. Jörg Heinrich

Head of QA/QC Separation
Technologies



Michael Rothhaar

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Quality Notification REPLY

Please complete and return this record by January 31, 2021 to

Email: Q.GQE-21-ST-001@Sartorius.com

Please enter below, which amount of packages of which material and lot number are within your stock and were quarantined following this notice:

Material Number	Lot number	Amount in stock

Please name the application you are using the filter in:

Reply Record Completed By:

(please print name)

Title:

(Please print)

The above measures have been carried out. We have informed all affected customers and have put the respective lot numbers in quarantine.

Return this Response Sheet with the information completed below as confirmation.

Signature / Date:

Name

Sales Company / Distributor/
Customer: