

Sartorius Stedim Biotech GmbH, 37070 Göttingen

15. January 2021

Urgent Field Safety Notice

Minisart® NML / Ophthalmart

FSCA ID : FSCA-2021-01-13

Safety measures for Minisart® NML / Ophthalmart

Dear Customer,

Details on affected devices:

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. The affected filters may not be suitable for medical device applications e.g. pharmacy admixture applications in a laboratory environment before use for patient care.

Usage of defective filters may result in a release of particles / fibers into the pharmacy admixture, which may be entered into the human body. Depending on the way of access into the body and the size and nature of the particles / fibers this may lead to foreign body reactions, immunological responses as well as pulmonary or cerebral microembolism and thrombosis.

Final impact is currently investigated with the goal to create a final list of affected products and lots. We will inform you as soon as reasonable possible, when additional information is available.

Sartorius Stedim Biotech GmbH
August-Spindler-Straße 11
37079 Göttingen, Germany
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Fax +49.551.308.3289
www.sartorius.com

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

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Advise on action to be taken by the user:

- Please identify and quarantine 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.
- Please review, if an event occurred after patient treatment associated with usage of the affected products and contact the reference person below if this is the case.
- Please inform us, how many filters you have on stock and how many have already been used by completing the attached form.

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.

Contact reference person:

....., Sartorius Stedim Biotech GmbH, August-Spindler-Str. 11, 37079
Gottingen, Phone +49 551 308 3712, Email:@sartorius.com

The undersign confirm that this notice has been notified to the appropriate Regulatory Agency.

We apologize for the related inconvenience.

Best regards
Sartorius Stedim Biotech GmbH

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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 by January 31, 2021 to

Sartorius Stedim Biotech GmbH

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August-Spindler-Str. 11

37079 Goettingen

Germany

Email:@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 Field Action has 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. Objective evidence about the execution of the Field Action is available on demand.

Signature / Date:

Name

Sales Company / Distributor/
Customer:
