

Sartorius Stedim Biotech GmbH, 37070 Göttingen

15. January 2021

Urgent Field Safety Notice

Minisart® NML / Ophthalsart

FSCA ID : FSCA-2021-01-13

Safety measures for Minisart® NML / Ophthalsart

Dear Customer,

Details on affected devices:

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

Description of the problem:

We identified syringe filters (Minisart® NML / Ophthalsart) 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
Phone +49.551.308.0
Fax +49.551.308.3289
www.sartorius.com

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

Managing Directors:
Uwe Becker,
Bettina Berendsen

Chairman of the Supervisory
Board:
Dr. Joachim Kreuzburg

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:

Iris Traut, Sartorius Stedim Biotech GmbH, August-Spindler-Str. 11, 37079
Gottingen, Phone +49 551 308 3712, Email: iris.traut@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
Manager Site Quality

Safety Officer Medical Devices



Dr. Anna Vreemann



Iris Traut

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Field Safety Corrective Action REPLY

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

Sartorius Stedim Biotech GmbH
Iris Traut
August-Spindler-Str. 11
37079 Goettingen
Germany
Email: iris.traut@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:

Annex Batch List (Initial Report)

Typ	Charge	Expiry date
16555-Q	90991103	06 / 2024
17594-GJR	91557103	10 / 2024
16534-K	90993103	06 / 2022
16534-K	00130103	01 / 2023
16534-K	00131103	01 / 2023
16534-K	00132103	01 / 2023
16555-K	90990103	06 / 2022
16555-K	90992103	06 / 2022
17594-GJR	91560103	10 / 2024
16534-K	00070103	01 / 2023
16534-K	00135103	01 / 2023
17594-GJR	91688103	11 / 2024
17598-K	91766103	12 / 2022
17597-K	90996103	06 / 2022
17594-GJR	00053103	01 / 2025
17594-GJR	00284103	02 / 2025
17594-GJR	00286103	02 / 2025
17594-GJR	00287103	02 / 2025
17594-GJR	00288103	02 / 2025
17594-GJR	00291103	02 / 2025
17594-GJR	00290103	02 / 2025
17597-K	00393103	03 / 2023
17594-GJR	00427103	03 / 2025
16555-GUK	00535103	04 / 2023
17594-GJR	00425103	03 / 2025
17594-GJR	00426103	03 / 2025
17594-GJR	00429103	03 / 2025
17594-GJR	00428103	03 / 2025
17594-GJR	00584103	04 / 2025
17594-GJR	00585103	04 / 2025
17594-GJR	00586103	04 / 2025
17594-GJR	00588103	04 / 2025
17594-GJR	00590103	04 / 2025
17598-Q	01172103	08 / 2025
16534-K	01112103	08 / 2023
17598-Q	01164103	08 / 2025
17597-Q	01131103	08 / 2025
17594-GJR	01159103	08 / 2025

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16555-Q	01189103	08 / 2025
16555-Q	01314103	09 / 2025
16555-Q	01317103	09 / 2025
16555-K	01192103	08 / 2023
16534-K	01249103	09 / 2023
16555-Q	01492103	10 / 2025
16555-K	01321103	09 / 2023
16555-Q	01494103	10 / 2025
17594-GJR	01359103	09 / 2025
16555-Q	01316103	09 / 2025
17528-K	01489103	10 / 2023
16534-GUK	01466103	10 / 2023
16534-K	01327103	09 / 2023
16534-K	01325103	09 / 2023
16555-K	01385103	10 / 2023
16534-K	200025103	11 / 2023