sartorius stedim biotech

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14 November 2018

Urgent Field Safety Notice

Minisart® NML, REF 16534----------K; LOT 80535103
FSCA ID : FSCA-2018-11-12
Return of Medical Device to the supplier

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

Managing Directors:
Uwe Becker,
Dr. René Fáber

Chairman of the Supervisory Board:
Dr. Joachim Kreuzburg

Date: 2018-11-14

Dear Customer,

Details on affected devices:
We delivered one or more packaging units of syringe filter Minisart® NML, article code 16534----------K, lot number 80535103 to you.

Description of the problem:
We identified some filters with wrong assembled membranes, i.e. 1.2 µm instead of 0.2 µm pore size. **These devices are not suitable for sterile filtration.**

The error can be detected by performing a post-use bubble point test. If the post-use bubble point test is passed, the corresponding filter is not affected by the quality issue described herein.

Usage of defective filters may result in a non-sterile filtrate that could cause a bacterial infection of the patient.

Advise on action to be taken by the user:

- Please identify and quarantine all filters of LOT 80535103. We will exchange them free of charge.
- Please return all filters of LOT 80535103 until **December 7, 2018** to **Distribo GmbH, Groner Siekanger 1, 37081 Goettingen, Germany** and give the ID Number: **FSCA-2018-11-12.**

- 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.
- Please complete the form attached and return it by **December 7, 2018** via email to the referenced contact person.

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:

Dr. Christian Hoffmann, Sartorius Stedim Biotech GmbH, August-Spindler-Str. 11, 37079 Gottingen, Phone +49 551 308 2406, Email: christian.hoffmann@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

Site Quality	Safety Officer Medical Devices
i. V. Hennig	i. A.
Dr. Hartmut Hennig	Dr. Christian Hoffmann

Field Safety Corrective Action
REPLY

Please complete and return this record by December 7, 2018 to

Sartorius Stedim Biotech GmbH
Dr. Christian Hoffmann
August-Spindler-Str. 11
37079 Goettingen
Germany
Email: christian.hoffmann@sartorius.com

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 recalled the respective lot numbers.

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: _____

_____

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