Sartorius Lab Instruments GmbH & Co. KG, 37070 Göttingen

Changenotification_ab@sartorius.com

July 07, 2023

Expected implementation date	Customer action required by Sartorius	Type of action
May 2024	No	N/A

Status Update: Renewed Reminder on the latest Status Updates for Minisart® Medical Devices

ECR 17832: Status update on the Change of Bubble Point Value for CE-Labeled Minisart® HY
ECR 24806: Change of Instruction for Use for the CE-labeled Minisart®
ECR 25981: Change of Labeling for the CE-Labeled Minisart®

Dear Valued Customer,

As you may already know, Europe is currently in the midst of transitioning to Medical Device Regulation (MDR) 2017/746. Many medical device manufacturers have been faced with declined Notified Body capacities, resulting in longer waiting times for notification of new changes. Unfortunately, this is also the case for Sartorius.

The latest changes (ECR17832, ECR24806, ECR25981) communicated in 2022 are still awaiting acknowledgement from our Notified Body. These changes can only be implemented after receiving official acknowledgment. Since we did not anticipate such extreme waiting timelines, we would like to remind you again about the most important and previously communicated changes and updates regarding Minisart® Medical Devices.

Change Description

ECR 17832: Change of Bubble Point Value for CE-Labeled Minisart® HY
The Bubble Point (BP) specification for CE-marked Minisart® HY filters with 0.2 µm pore size has been reduced to 1.1 bar (16 psi).

ECR 24806: Change of Instruction for Use for the CE-labeled Minisart®
To ensure the integrity of the filter, the maximum operating pressure for Minisart® HY/SRP in the direction OUT-IN should not exceed 1 bar. Despite the restriction, it is still possible to draw up solutions through the filter since this only creates a vacuum of less than or equal to 1 bar.

In addition, the use of the EO sterilized Minisart® syringe filters must be restricted. They can no longer be used for premature neonates, stem cell and embryo related applications, to exclude any risk of EO residuals.

Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Straße 20
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
HRA 201253

The company is a limited commercial partnership

Individually liable shareholder

Sartorius Weighing Technology GmbH
Registered Office:
Göttingen
Local Court of Registration:
Amtsgericht Göttingen
HRB 201458
Managing Directors:
Mario Hespe,
Carsten Wolter

ECR 25981: Change of Labeling for the CE-Labeled Minisart®. To comply with the new ISO standard 15223-1 (Medical devices — Symbols to be used with information to be supplied by the manufacturer), Sartorius has revised the packaging labels and Tyvek foil label of the CE-labeled Minisart® product portfolio. The change affects only the products labeling. The production facility and production processes remain completely unchanged.

Impacted Products

The list of impacted products can be found in Appendix I.

Change Implementation

This change is controlled internally in accordance with Sartorius change management procedures.

This change will be implemented latest from May 2024, onwards. The first deliveries are planned for May 26, 2024.

We continuously strive to implement solutions to our products and services to enable you to get your treatments to patients faster. We thank you for your trust and continued use of Sartorius products, and we look forward to assisting you in managing this change.

Sincerely,

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Fiona Coats
Signer Name: Fiona Coats
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Fiona Coats
Head of Marketing LPS
Sartorius Corporation

Susanne Gerighausen
Head of Quality Assurance & Control LPS
Sartorius Lab Instruments GmbH & Co. KG

Note: List of affected manufacturing sites of impacted products:
- Sartorius Stedim Biotech GmbH, Goettingen, Germany
- Sartorius Lab Instruments GmbH & Co. KG, Goettingen, Germany
- Sartorius Stedim Plastics GmbH, Goettingen, Germany

Appendix I

ECR17832: Impacted Products

Material number	Material description
16596--------HYK	MinisartPTFE_0,2Âµm_26mm_sterile_50p
16596--------HYQ	MinisartPTFE_0.2Âµm_26mm_nsterile_50
16599--------HYQ	MinisartPTFE_0,2µm_26mm_nsterile_500
16596--------ZSK	MinisartPTFE_0,2Âµm_26mm_sterile_50p

ECR 24806 and ECR 25981: Impacted Products

Material number	Material description
16534--------GUK	MinisartCA_0,2µm_28mm_gsterile_50pc
16534----------K	MinisartCA_0,2Âµm_28mm_sterile_50pc
16534----------Q	MinisartCA_0,2Âµm_28m_nsterile_500pc
16555--------GUK	MinisartCA_0,45Âµm_28mm_gsterile_50p
16555----------K	MinisartCA_0,45 µm_28mm_sterile_50pc
16555----------Q	MinisartCA_0,45Âµm_28mm_nsterile_500
17597----------K	MinisartCA_0,2Âµm_28mm_sterile_50pc
17597----------Q	MinisartCA_0,2Âµm_28mm_nsterile_500p
17598----------K	MinisartCA_0,45Âµm_28mm_sterile_50pc
17598----------Q	MinisartCA_0,45Âµm_28mm_nsterile_500
17528----------K	Ophthalsart
16596--------HYK	MinisartPTFE_0,2Âµm_26mm_sterile_50p
16596--------HYQ	MinisartPTFE_0.2Âµm_26mm_nsterile_50
16599--------HYQ	MinisartPTFE_0,2µm_26mm_nsterile_500
16596--------ZSK	MinisartPTFE_0,2Âµm_26mm_sterile_50p
17575--------ACK	MinisartPTFE_0,2Âµm_25mm_sterile_50p
17594--------GJR	MinisartNML_CA 5µm_ 28mm_ gamma-ste_
17594----------K	MinisartCA_5,0Âµm_28mm_sterile_50pc