

February 17, 2022

Notification Letter**ECR 17832: Change of Bubble Point Value for CE-Labeled Minisart® HY**

Dear Valued Customer,

This letter is intended to inform you of the change of Bubble Point value for CE-marked Minisart® HY filters.

Change Description

Based on customer feedback, the Bubble Point (BP) specification was reduced for CE-marked Minisart® HY filters with 0.2 µm pore size.

The BP value is correlated with the sterile filtration capability of a filter and is tested and proven by a bacteria challenge test (BCT) with *Brevundimonas diminuta*. The BP test is used to determine the integrity of filters before and/or after use. The current minimum BP value to consider a filter integral and sterilizing is 1.4 bar (20 psi).

Investigations after customer feedback revealed that all Minisart® HY syringe filters with BP values ≥ 0.95 bar (14 psi) already produce sterile filtrates in accordance with the BCT.

It was therefore decided to decrease the minimum BP value with a security surcharge of 0.15 bar to 1.1 bar (16 psi).

This information is documented in the current brochures, user manuals and datasheets. All these documents will be updated to the new specification.

Current BP value specification for CE-Minisart® HY with 0.2 µm pore size (with ethanol)	BP value specification for CE-Minisart® HY with 0.2 µm pore size (with ethanol) after change
≥ 1.4 bar (20 psi)	≥ 1.1 bar (16 psi)

This change has no impact on the product form, fit or function. The production facility and production processes remain completely unchanged.

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:
Brauer, Peer;
Hespe, Mario;
Wolter, Carsten

Impacted Products

16596-----HYK	MinisartPTFE_0,2µm_26mm_sterile_50p
16596-----HYQ	MinisartPTFE_0,2µm_26mm_nsterile_50
16599-----HYQ	MinisartPTFE_0,2µm_26mm_nsterile_500
16596-----ZSK	MinisartPTFE_0,2µm_26mm_sterile_50p

Change Implementation

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

The change of the related product specification will become valid from March 1st, 2022.

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 look forward to assisting you in managing this change.

Sincerely,



Fiona Coats
Head of Marketing LPS
Sartorius Corporation



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