

Sartorius Lab Instruments GmbH & Co. KG, 37070 Göttingen

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April 29, 2024

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

Status Update

ECR 33958: Change of Labeling, Acceptance Criteria for Growth Promotion Test and Update Shelf Life of Nutrient Pad Sets

Dear Valued Customer,

This Status Update is to inform you about several ongoing changes for our Nutrient Pad Sets. These changes relate to a previous change notification letter, which was send out in June 2023. It includes a change of product labeling, release testing and update in shelf-life information for the Nutrient Pad Sets.

Change Description

Nutrient Pad Sets are dehydrated culture media pads in a petri dish with a suitable membrane filter, which are used in the Microbiological Quality Control of beverages and of environmental water samples.

In our previous notification letter (ECR 33958: Change in Production Process for Nutrient Pad Sets, dated June 20, 2023), we informed you that there would be a change in the content of the product labels and the shortage of the shelf-life, among other topics.

In the meantime, we have received new results from the running validation and shelf-life study, which have led us to implement the following changes:

Sartorius Lab Instruments GmbH & Co. KG

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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

1. Shelf Life of Nutrient Pad Sets:

In our letter dated June 20, 2023, we informed you that we intended to temporarily reduce the shelf life of our Nutrient Pad Sets to 1 year until the results of the 2-year shelf-life study was available. In the meantime, the data from the 1-year shelf-life study are now available. The results in the field of microbial growth, appearance, and sterility of the NPS have met all acceptance criteria.

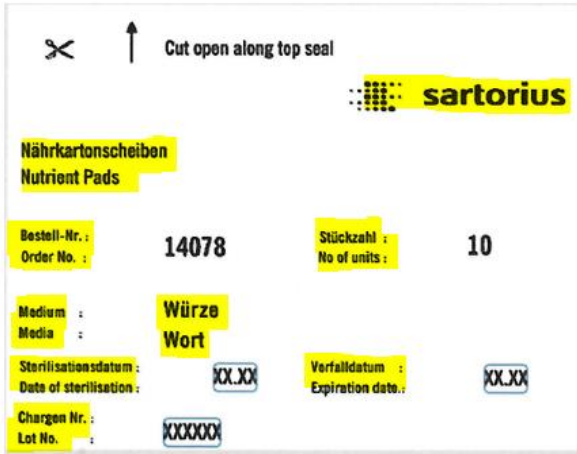



On this basis, we are increasing the shelf life on a risk-based approach with the successful results of the 1-year shelf-life study. We will therefore continue to produce our NPS with a shelf life of 2 years after switching to the optimized production process.

2. Acceptance Criteria of the Growth Promotion Test:

After the implementation of the new production process with a low bacterial load, we changed the acceptance criteria of the Nutrient Pad Sets from 90% (percentage of test batch compared to a specific agar control by membrane filtration method) to 70% (percentage of test batch compared to a specific agar control by plate count method). This change is based on the test specifications from DIN EN ISO 11133:2020-10. The validity of the adapted acceptance criteria has been demonstrated by the successful results of the validation for the new production processes as well as the results of the 1-year shelf-life study.

3. Adaptation of Product Labels

As part of our ongoing efforts to improve the user experience of our products, we have also decided to revise and simplify the labels on the primary and secondary packaging of the products affected by this change. Consequently, additional information such as the manufacturing date, expiry date, number of units, order number, and lot number will be added to the label. Furthermore, the German translation will be removed from the labels, and the Sartorius logo will be updated. Finally, a disclaimer stating "For single use only" will be added to the secondary packaging. A comparison of the old and new packaging labels can be found in the table below.

Old print of the label on the primary packaging (Aluminum bag)	New print of the label on the primary packaging (Aluminum bag)
	
Old print of the label on the secondary packaging	New print of the label on the secondary packaging
	

Impacted Products

The list of impacted products can be found in Appendix 1.


Change Implementation


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

These changes will be implemented with immediate effect.

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,

DocuSigned by:
Fiona Coats
 Signer Name: Fiona Coats
Signing Reason: I approve this document
Signing Time: 2024-04-30 | 01:19:15 CEST
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DocuSigned by:
Susanne Gerighausen
 Name des Unterzeichners: Susanne Gerighausen
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 2024-05-06 | 08:40:30 MESZ
165B30A4A29E4CD99853CE51CFCFDDBF

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 site(s) / manufacturing site(s) of impacted products
- Sartorius Lab Instruments GmbH & Co. KG, 37070 Göttingen, Germany
- Sartorius Stedim Biotech GmbH, 37070 Göttingen, Germany

Appendix 1: Please refer to the document attached.