

Sartorius Lab Instruments GmbH & Co. KG, 37070 Göttingen

Changenotification_ab@sartorius.com

June 20, 2023

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

Notification Letter

ECR 33958: Change in Production Process for Nutrient Pad Sets

Dear Valued Customer,

This notification letter is to inform you of a change within the production process of the Nutrient Pad Sets.

Change Description

Nutrient Pad Sets are dehydrated culture media pads in a petri dish with a suitable membrane filter. The Cellulose Pads are impregnated with Nutrient Media and dehydrated afterwards to guarantee a long shelf life of 2 years. Before using this type of media, the Nutrient pads needs to be activated with 3,5 ml of sterile water. Nutrient Pad Sets are used in the Microbiological Quality Control of beverages and of environmental water samples.

Due to new regulations and safety restrictions, an internal Ethylene Oxide (EtO) sterilization of semi-finished goods used in the manufacture of Nutrient Pads in our production site is no longer feasible. In future, instead of sterilization of the Nutrient Pads we will produce the product in a germ reduced environment.

This change will include following topics:

1. Discontinuation of internal EtO sterilization of Nutrient Pads
2. Change of sterility testing in the final control
3. Change of sterility claim on labels and certificate
4. Reduced Shelf life (interim)

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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

Technical Package

A Comparability & Impact Assessment is provided with this letter (Table 1). A summary of the validation report can be requested after 1 year shelf life in January 2024 and after 2 years shelf life (+ 3 months) from April 2025, onwards at the address Changenotification_AB@sartorius.com.

Table 1: Comparability & Impact Assessment of the process change

Comparability & Impact Assessment			
Items	Old process	New Process	Impact on final Product Critical Quality Attribute
Product Packaging	No Change		No impact
Raw materials	No Change		No impact
Components	No Change		No impact
Packaging materials	No Change		No impact
Manufacturing process	Mixing and boiling the media components in an open container; Impregnating of the Cellulose Pads in an ISO class 8 environment; EtO sterilization of the impregnated Cellulose Pads	Implementation of autoclaving step of liquid media (or sterile filtration of some heat sensitive components), impregnation of the sterile Cellulose Pads with sterile liquid media in a low bioburden production process: improved production environment (class 7); Improved clothing concept, sterilization of production accessories, additional cleaning of production rooms and machines, implementation of monitoring steps during production	No impact on the final product quality
Labelling	Information on label (aluminium bag and carton box): Sterilisationsdatum/ Date of Sterilization	Information on label (aluminium bag and carton box): Herstellungsdatum/ Date of Production	Change of label

Sterilization	EtO sterilization of impregnated Cellulose Pads (not the end product)	No EtO sterilization of the impregnated Cellulose Pads	Change in sterilization, given the improvements in the manufacturing environment
Sterility Test: 1. Number of test units per lot	10 units of the end product per lot	Sample size according to ISO 2859-1: AQL level* (Acceptance Quality Limit) of 1,0%, general inspection level II	Significant increase in the number of samples tested to ensure product quality
Sterility Test: 2. Test Method	Test units of the end product are incubated for 5-7 days at 30-35°C after adding 5ml of sterile water into the petri dishes	No Change	No change in the test method
Quality Assurance Certificate	"Each manufacturing lot was sampled, tested and released by Quality Assurance with respect to the following characteristics: ▪ Sterility"	"Sampled according to ISO 2859-1: AQL (Acceptable Quality Limit) 1,0%, general inspection level II; Incubation after 5-7 days at 30-35°C: Passes release criteria"	Modification of the certification to reflect the change
Shelf life	2 years shelf life	Change shelf life interim from 2 to 1 year (for products produced in 2024). After successful finalization of the shelf-life study, shelf life will be increased to 2 years or more	Shorter shelf (initially for 1 year, until completion of the extended shelf-life study) for products produced in 2024

*The acceptable quality level (AQL) is a measure applied to products and defined in ISO 2859-1 as a statistical measurement of the maximum number of acceptable defects in a given sample. In other words, the AQL is a measure of product quality when a sample is drawn at random and checked to meet design specifications and design criteria. The AQL tells you how many defective (in this case contaminated) components are considered acceptable during random sampling quality inspections. It is usually expressed as a percentage or ratio of the number of defects compared to the total quantity.

This change has no impact on the color of the media, pH value, selectivity, recovery rate or the quality of the final product.

Impacted Products

Please find the list with impacted products in the Appendix 1.


Change Implementation


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

This change will be implemented from January 2024, onwards.

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: 2023-06-20 | 16:21:01 CEST
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DocuSigned by:
Susanne Gerighausen
 Name des Unterzeichners: Susanne Gerighausen
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 2023-06-20 | 13:54:56 MESZ
165B30A4A29E4CD99853CE51CFCFDDBF

Fiona Coats
Head of Marketing LPS
Sartorius Corporation

Susanne Gerighausen
Head of Quality Assurance and 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

Appendix 1: See document attached