Sartorius Stedim Biotech GmbH, 37070 Göttingen

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May 10th, 2021

Notification Letter
ECR 23559, ECR 23591, ECR 23638– EPA Product Label Change-Addition of Direction of Use Statement

Dear Valued Customer,

As a leading international supplier of process technologies to the biopharmaceutical and life science industry, Sartorius is committed to continuous improvement of our products and services in order to better serve our customers.

This notification letter is intended to inform you about the addition of the direction for use statement for Bioprocess and Laboratory products.

Change Description

Sartorius is requested to assure regulatory compliance to EPA regulations. To fulfill the current labeling requirements, information about the Direction for Use shall be added on the product label of FIFRA relevant products. Please find an example in appendix 1.
All existing specifications, raw materials used for production, manufacturing procedures and the relevant product documentation remain completely unchanged and fully valid. This change does not have any impact on the form, fit or function of the supplied products, and does not have regulatory impact for customers.

Impacted Products

The above-mentioned change is implemented to a wide range of products of our Bioprocess- and Laboratory product families:

Aerosart, Midisart, Sartofluor, Sartovent, Vacusart, Aquasart, Sartocon, Filter Transfer Sets, Flexboy bags, Flexel bags, Flexsafe Bags, Minisart, Sartolab, Arium, Membrane filtration, Sartobind, Vivapure, Sartobran, Sartoclean, Sartoclear, Sartocool, Sartoguard, Sartolon, Sartopore, Smart Consumables, Vinosart, Virosart.

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Dr. Joachim Kreuzburg

Change Implementation

This change is controlled internally according to our change management procedures and will be managed with full lot traceability.

The described change of the Direction for Use statement, required for label compliance, will be implemented on May 31st 2021.

We appreciate your trust and your continuous use of Sartorius Stedim Biotech GmbH filter products. We are looking forward to support you in every way possible. If you have further questions, please do not hesitate to contact your local Sartorius Sales Representative.

Sincerely,

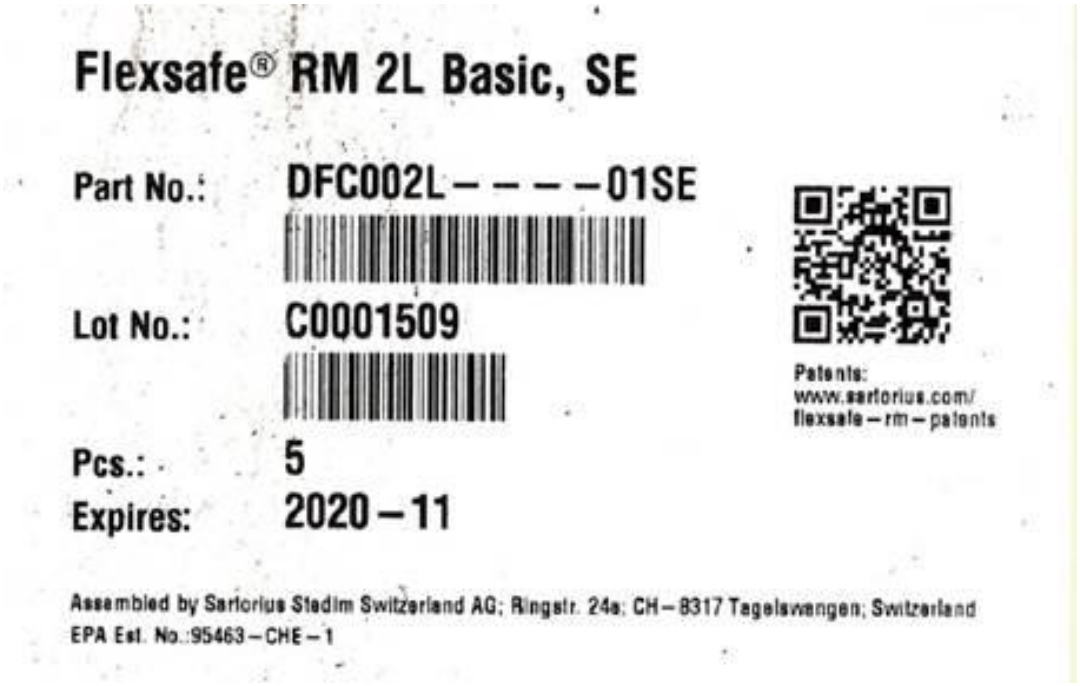
Fritjof Heinrich Linz
Head of Product Management Separation
Sartorius Stedim Biotech GmbH

Vanessa Nardolillo
Head of Quality Management & Regulatory affairs BPS
Sartorius Stedim FMT SAS

Appendix 1

Example of Label

Old Label



New Label