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Notification letter

ECR 18839_Change of labeling for the CE-labeled Minisart®

Dear Valued Customer,

As an international leading supplier of high-quality laboratory instruments and consumables, Sartorius is implementing measures on an ongoing basis to improve the quality of its products and services.

This letter is to inform you about a change of labeling for the CE-labeled Minisart® product portfolio.

Within the framework of the new Medical Device Regulation (MDR, 2017/745) we will face changes due to increased regulatory requirements. To fulfil the new requirements, we are revising the labeling and documentation. The relevant materials are listed below:

- 1) Label
- 2) Instructions for Use

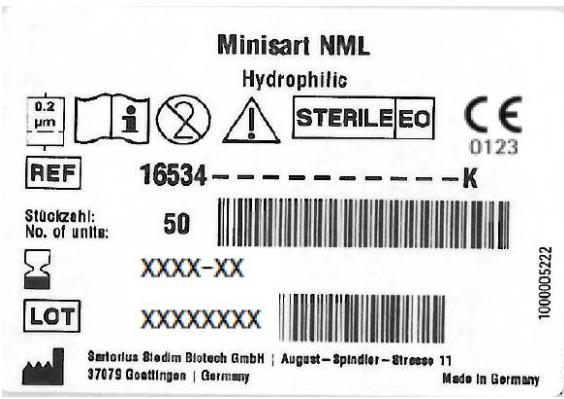
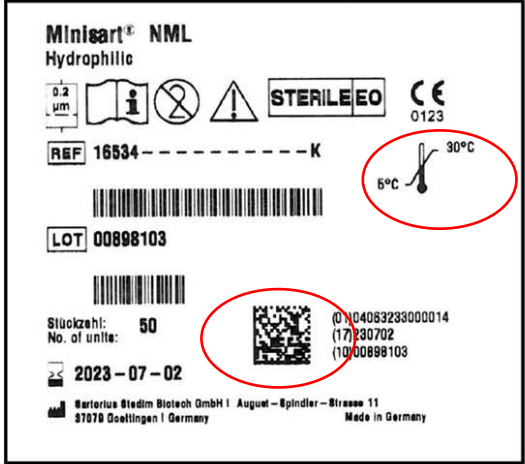
Change Description

To comply with the new regulation, we have revised our label and instructions for use of the CE-labeled Minisart® product portfolio. Additionally, we will provide the instruction for use in all defined official languages of the member states of the EU.

In this context we would like to achieve a clear distinction between the CE-Minisart® and the standard Minisart product portfolio therefore we make layout changes in the marketing material.

Furthermore, for better traceability, we have implemented the UDI-code on the labels.

The below images illustrate the changes to the label.

Pre-change labelling	Post-change labelling
	
Size: 70x 52 mm	Size: 70x 66 mm

In this revision process, Sartorius noticed that there is a typographical error in the instructions for use and marketing material for the specified flow rate value and used solvent for Minisart SRP 0.2 µm.

The below table illustrates the changes to the flow rate value and water penetration point.

Flow rate	Current situation	After Change
at 1 bar	160mL/min	60mL/min
Solvent	Methanol	Ethanol

The changes do not have any impact on the product function, or the production facility and production processes remain completely unchanged. The LF catalogue, brochure and website will be updated incrementally.

Affected products

type 16534, 0.2 µm, packs K GUK Q
type 17597, 0.2 µm, packs K Q
type 16555, 0.45 µm, packs K GUK Q
type 17598, 0.45 µm, packs K Q
type 17594, 5.0 µm, packs K GJR
type 17528, 0.2 µm, pack K
type 16596, 0.2 µm, packs HYK HYQ
type 16599, 0.2 µm, pack HYQ
type 17575, 0.2 µm, pack ACK

Change Implementation

This change is controlled internally according to our change management procedures.

This change will be implemented as of April 2021 in the course of new productions.

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 Product Management, LPS
Lab Instruments GmbH & Co.KG



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