

Sartorius Lab Instruments GmbH & Co. KG, 37070 Göttingen

Changenotification_ab@Sartorius.com

March 22, 2022

Change Notification Letter
ECR 25981: Change of Labeling for the CE-Labeled Minisart®

Dear Valued Customer,

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

Change Description

To maintain the regulatory state of the art, Sartorius have revised the packaging labels and Tyvek foil label of the CE-labeled Minisart® product portfolio, in order to be compliant with the new ISO standard 15223-1 (Medical devices – Symbols to be used with information to be supplied by the manufacturer).

The below images illustrate the changes to the label

Pre-change labelling	Post-change labelling
Label	Label

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

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

Pre-change labelling	Post-change labelling
Legend	
	European conformity
	Consult instructions for use
	Single Use
	Sterilized, EO
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside

Pre-change labelling	Post-change labelling
Legend	
	Do not re-sterilize
	Non-pyrogenic
	Medical Device
	Do not use if the packaging is damaged
	Protect from exposure to light
	Keep dry
	Maximum and minimum temperature
	Order Number
	Use before
	Lot Number

Pre-change labelling	Post-change labelling
Legend	
	Manufacturer

The change affects only the products labeling. The production facility and production processes remain completely unchanged.

Impacted Products

Please find impacted Medical Devices below:

Part number	Description
16534-----GUK	MinisartCA_0,2µm_28mm_gsterile_50pc
16534-----K	MinisartCA_0,2Åµm_28mm_sterile_50pc
16534-----Q	MinisartCA_0,2Åµm_28m_nsterile_500pc
16555-----GUK	MinisartCA_0,45Åµm_28mm_gsterile_50p
16555-----K	MinisartCA_0,45 µm_28mm_sterile_50pc
16555-----Q	MinisartCA_0,45Åµm_28mm_nsterile_500
17597-----K	MinisartCA_0,2Åµm_28mm_sterile_50pc
17597-----Q	MinisartCA_0,2Åµm_28mm_nsterile_500p
17598-----K	MinisartCA_0,45Åµm_28mm_sterile_50pc
17598-----Q	MinisartCA_0,45Åµm_28mm_nsterile_500
17528-----K	Ophthalsart
16596-----HYK	MinisartPTFE_0,2Åµm_26mm_sterile_50p
16596-----HYQ	MinisartPTFE_0,2Åµm_26mm_nsterile_50
16599-----HYQ	MinisartPTFE_0,2µm_26mm_nsterile_500
16596-----ZSK	MinisartPTFE_0,2Åµm_26mm_sterile_50p
17575-----ACK	MinisartPTFE_0,2Åµm_25mm_sterile_50p
17575-----ZSK	Minisart SRP 25 0.2Åµm sterile single pa
17594-----GJR	MinisartNML_CA 5µm_28mm_gamma-ste_
17594-----K	MinisartCA_5,0Åµm_28mm_sterile_50pc

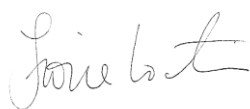
Change Implementation

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

This change will be implemented as of March 2022, in the course of new productions.

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,



Fiona Coats
Head of Marketing LPS
Sartorius Corporation



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