Sartorius Lab Instruments GmbH & Co. KG, 37070 Göttingen

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March 22, 2022

Change Notification Letter
ECR 24806: Change of Instruction for Use 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

As part of continuous improvement of safety for our patients and to fulfil the requirements of the Medical Device Regulation (MDR, 2017/745), we are revising and restructuring the impacted products instruction for use and all warnings. For a better overview, we decided to provide updates to the instructions for use, which will be provided in all defined official languages of the member states of the EU, and in English, for each individual product family listed below:

1. 0.2/0.45 µm Minisart® NML/Ophthalsart
2. 5.0 µm Minisart® NML and
3. 0.2 µm Minisart® HY/SRP.

During the review and restructuring of the instruction for use, an inconsistency in the specification of the bidirectional use for Minisart® HY/SRP was identified. Contrary to the information in the current instruction for use, the maximum operating pressure for Minisart® HY/SRP in the direction OUT-IN should not exceed 1 bar, in order to guarantee the integrity of the filter. Despite the restriction, it is still possible to draw up solutions through the filter since this only creates a vacuum of less than or equal to 1 bar.

Furthermore, the use of the EO sterilized Minisart® syringe filters must be restricted. They can no longer be used for premature neonates, stem cell and embryo related applications, to exclude any risk of EO residuals.

The changes do not have any impact on the production facility, and production processes remain completely unchanged.

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HRA 201253

The company is a limited commercial partnership

Individually liable shareholder

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Registered Office:
Göttingen
Local Court of Registration:
Amtsgericht Göttingen
HRB 201458
Managing Directors:
Brauer, Peer;
Hespe, Mario;
Wolter, Carsten

Impacted Products

Please find impacted Medical Devices below:

Part number	Description
16534--------GUK	MinisartCA_0,2µm_28mm_gsterile_50pc
16534----------K	MinisartCA_0,2Âµm_28mm_sterile_50pc
16534----------Q	MinisartCA_0,2Âµm_28m_nsterile_500pc
16555--------GUK	MinisartCA_0,45Âµm_28mm_gsterile_50p
16555----------K	MinisartCA_0,45 µm_28mm_sterile_50pc
16555----------Q	MinisartCA_0,45Âµm_28mm_nsterile_500
17597----------K	MinisartCA_0,2Âµm_28mm_sterile_50pc
17597----------Q	MinisartCA_0,2Âµm_28mm_nsterile_500p
17598----------K	MinisartCA_0,45Âµm_28mm_sterile_50pc
17598----------Q	MinisartCA_0,45Âµm_28mm_nsterile_500
17528----------K	Ophthalsart
16596--------HYK	MinisartPTFE_0,2Âµm_26mm_sterile_50p
16596--------HYQ	MinisartPTFE_0.2Âµm_26mm_nsterile_50
16599--------HYQ	MinisartPTFE_0,2µm_26mm_nsterile_500
16596--------ZSK	MinisartPTFE_0,2Âµm_26mm_sterile_50p
17575--------ACK	MinisartPTFE_0,2Âµm_25mm_sterile_50p
17575--------ZSK	Minisart SRP 25 0.2Âµm sterile single pa
17594--------GJR	MinisartNML_CA 5µm_ 28mm_ gamma-ste_
17594----------K	MinisartCA_5,0Âµm_28mm_sterile_50pc

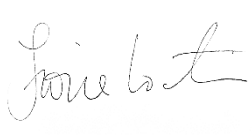
Change Implementation

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,



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