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HRB No. 200266

Sartorius Stedim Biotech GmbH 37070 Goettingen Germany

## Notification letter

ECR 17617

### Improvement of the distinctiveness of the lot number system of certain Bioprocess and Laboratory products

#### Addition of one digit to the current lot number system encoding the “Year of Manufacture”

Dear Valued Customer,

As an international leading supplier of process technologies to the bio-pharmaceutical and life science industry Sartorius Stedim Biotech GmbH is committed to a continuous improvement of its products and services in order to serve our customers in an optimal way.

This notification letter is intended to inform you about the addition of one digit to our lot number system for Bioprocess and Laboratory products.

#### Description

Sartorius products delivered to the bio-pharmaceutical and life science industry can be fully traced back by our lot numbering system and the subsequent product related documentation.

The structure of the Sartorius lot number system follows a defined logic and is assuring together with our documentation system complete traceability of the manufacturing process and the raw materials used for production of our products.

Depending on the product group the length of the lot number is defined to either 8 or 9 digits.

The structure of these lot numbers is defined as follows:

Legend		Number of digits Current Lot number	Number of digits Future Lot number
Y	Year of Manufacture	1	2
CW	Calendar Week of Manufacture	2 (if applicable)	2 (if applicable)
N	Consecutive Number	4	4
P	Production Line	1 or 2 (depending on production line)	1 or 2 (depending on production line)
T	Tool	1 (if applicable)	1 (if applicable)
X	Plant	1	1

Within the structure of our lot number system, the first digit of a lot number is encoding the year of manufacturing. As an example the lot number of a product manufactured in the current year 2020, would carry the digit "0" as first digit of its lot number.

Considering using only 1 digit to encode the "Year of Manufacture", there is a potential risk that after a period of 10 years a lot number used already for a certain product code could be used again for a newly produced lot of the same product code.

In order to avoid such potential occurrence of using the same lot number for production of the same product within a 10 years time frame, Sartorius will implement an additional digit to its lot number. Thereby the "Year of Manufacture" will be encoded by two (2) digits in the future. The remaining structure of our lot number system, as explained above, will not be changed.

The lot number continues to appear on the label of the product, the Quality Assurance Certificate, as well as on the product itself, please find examples in attachment 01.

### Affected Product Lines

The above mentioned change is implemented to a wide range of products of our Bioprocess- and Laboratory products (please see attachment 02).

### Bioprocess Products:

Standard Filter Cartridges & Mini-Cartridges

Quickseal

MaxiCaps & MidiCaps & Capsules

Sartobind Devices

Crossflow Cassettes

Virosart Devices

Midisart

OPTA Sterile Connectors

Sartoclear & Sartobind Devices

## Laboratory Products:

Minisarts incl. custom version  
Sartolab P 20 Devices  
Sterisart Devices

The attached files provide you an detailed overview on each order code for which the additional digit will be added to the respective lot number.

## 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 number of digits of the lot number of the affected products will be implemented on Nov 1<sup>st</sup> 2020.

During the initial implementation phase of this change it may happen that you receive products labeled with the unchanged batch number structure as well as products labeled with the adjusted batch number structure

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.

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 Stedim Biotech GmbH representative.

Sincerely,



i.V. Fritjof Linz  
Head of Product Management Separation  
Sartorius Stedim Biotech GmbH



i.V. Vanessa Nardolillo  
Head of Quality Management and  
Regulatory Affairs  
Sartorius Stedim FMT SAS

## Attachment 01

### Labels :

Batch Number for following material is

Old Batch format YnnnnPPX

New Batch Format YYnnnnPPX



### Certificate:

Batch Number for following material is

Old Batch format YnnnnPPX

## Quality Assurance Certificate

	<b>Sartolab P</b>
Order no.	18052-----D
Use before	04 / 2023
Pore size	0.20 µm
Lot no.	00016116

Sartolab is manufactured by Sartorius in accordance with the Current Good Manufacturing Practice Standards and in a facility whose Quality Management System is certified for compliance with the DIN EN ISO 9001 Quality System Standard.

This product was sterilized using a validated process following DIN/EN ISO 11135 regulations.

New Batch Format YYnnnnPPX

## Quality Assurance Certificate

	<b>Sartolab P</b>
Order no.	18052-----D
Use before	08 / 2023
Pore size	0.20 µm
Lot no.	200016116

Sartolab is manufactured by Sartorius in accordance with the Current Good Manufacturing Practice Standards and in a facility whose Quality Management System is certified for compliance with the DIN EN ISO 9001 Quality System Standard.

This product was sterilized using a validated process following DIN/EN ISO 11135 regulations.