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September 21, 2020

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## Notification letter

**ECR 19015:** Update in the Barcodes content of selected Flexboy® product labels

Dear Valued Customer,

### Introduction



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

This change notification is written to inform you about the update of the content in the product labels barcodes of selected Flexboy® products.

### Change description

In the perspective of our process digitalization, Sartorius will replace barcodes by 2 Dimensions Data Matrix to automatize the product units counting.

The table below illustrates the concept of this update:

	Before	After implementation
Type of barcode	1 Dimension barcode 	2 Dimensions Data Matrix 
Content of the Barcode (for internal use)	Lot number	[Lot number] & [counter number] & [Qty number]

Example of current and new labels are illustrated in the appendix. Those labels are on the product packaging bag and on boxes.

This change does not affect the quality of the product.

This change is only documentation related, there is no impact of the change on the finished products themselves.

## Impacted Products

Only a restrained number of references will have this new barcode implemented.

This change will impact only the following products:

FFB101961  
FFB101974  
FFB102025  
FFB102340  
FFB102603  
FFB102606  
FFB102704  
FFB103412  
FFB103449  
FFB103543  
FFB103546  
FFB110904  
FFB110905  
FFB110906  
FFB110907  
FFB110912


## Change Implementation

This change is controlled internally according to our change management procedures. It will not require a revision of the Technical Drawing (TD).

For the products listed above, the change will be implemented from December 2020.

We thank you for your trust and your continuous use of Sartorius products and look forward to assisting you in managing this change.

Sincerely,



Dr Eva Lindskog  
Head of Marketing FMT  
Sartorius Stedim Switzerland AG



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

## Appendix: labels before and after the change

Label before	Label after
<p>REF CODE </p> <p>NPCB unit(s) </p> <p>DESCRIPTION</p> <p>CUSTOMER DESC</p> <p>CUSTOMER CODE</p> <p> NON PYROGENIC FLUID PATH <input type="text" value="STERILE"/> <input type="text" value="R"/> <input type="text"/></p> <p>Store at ambient temperature in a dry place. Do not use if package is damaged, caps are loose or if any leak is found.</p> <p> FAB.  DATE</p> <p><input type="text" value="LOT"/> LOT </p> <p> Release site address <span style="float: right;">Assembled in Country</span> <b>COMP</b></p>	<p>REF CODE </p> <p>NPCB unit(s) </p> <p>DESCRIPTION</p> <p>CUSTOMER DESC</p> <p>CUSTOMER CODE</p> <p> NON PYROGENIC FLUID PATH <input type="text" value="STERILE"/> <input type="text" value="R"/> <input type="text"/></p> <p>Store at ambient temperature in a dry place. Do not use if package is damaged, caps are loose or if any leak is found.</p> <p> FAB.  DATE </p> <p><input type="text" value="LOT"/> LOT </p> <p> Release site address <span style="float: right;">Assembled in Country</span> <b>COMP</b></p>
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