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## Change Notification

### ECR 016370: Optimization of Sartobind® Nano Capsule Design and Labelling ECR 021276: Change of Sartobind® Nano Laser Labelling

Dear Valued Customer,

As a worldwide leading provider of process technologies to the bio-pharmaceutical industry, Sartorius Stedim Biotech GmbH is committed to continuously improving its products and services to best serve its customers.

We are pleased to announce that we are optimizing our Sartobind® nano capsule labelling and design in order to align with the new ISO norm 80369-7 for Luer connectors.

## Change description

The injection molding tool for our Sartobind® nano capsule was adapted to ISO norm 80369-7 (small-bore connectors for liquids and gases in healthcare applications) which includes the Luer connector. In addition, the molding form was optimized to state-of-the-art manufacturing technologies. This allows us to maintain a consistent product quality of the nano capsule and to assure the adapted ISO standards for connectivity. The fluid path within the nano capsule is maintained as well as the performance (see below). Scalability to our Sartobind® device family is maintained as well.

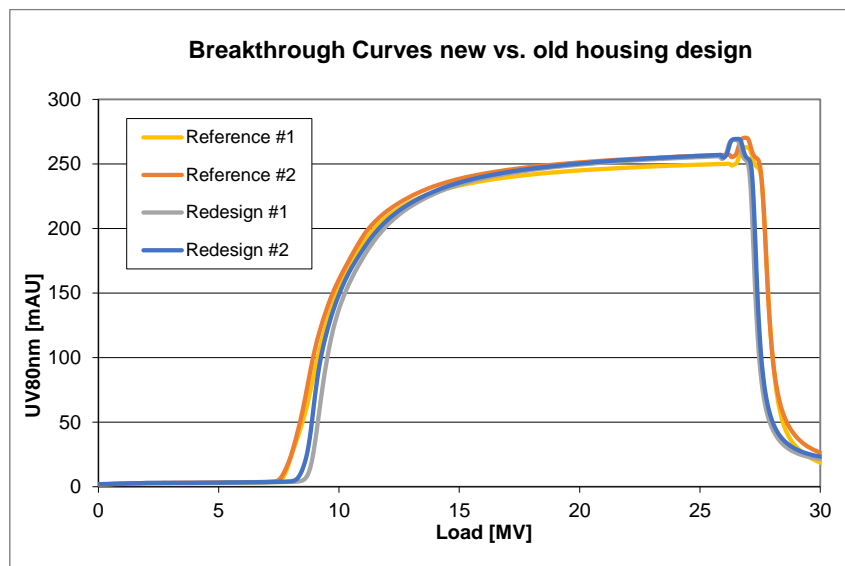
Visual comparison of recent (left) and new (right) Sartobind® nano capsule design



Dimensions of the Sartobind® nano capsule

	Recent design	New design
Height	37 mm	37 mm
Outer Diameter	33 mm	31 mm

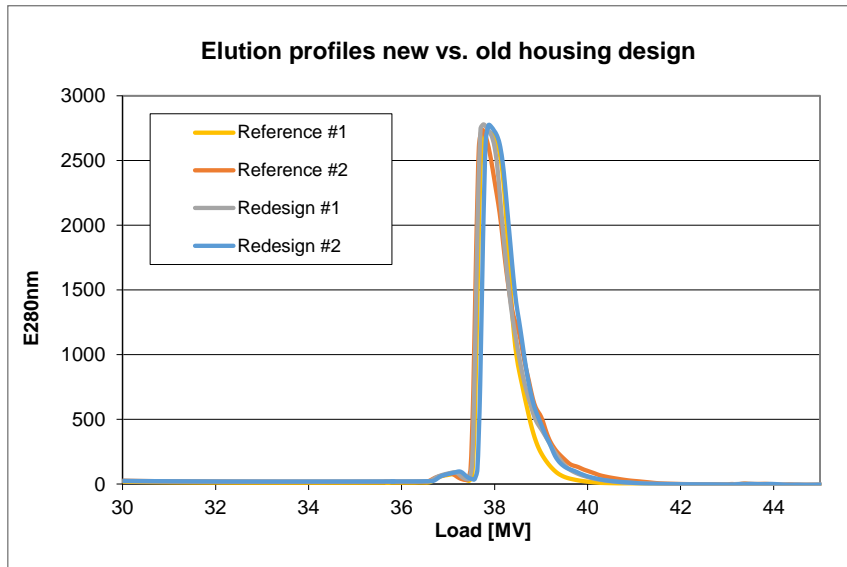
Functional comparison of recent and new Sartobind® nano capsule design



Breakthrough curves and elution profiles are shown using Sartobind® Q nanos as an example which were loaded with bovine serum albumin (Load: 2 g/L in 20 mM Tris/HCl pH 7.2).

Reference:  
recent Sartobind® nano design

Redesign:  
new Sartobind® nano design



Comparison of recent (left) and new (right) labelling of Sartobind® nano products:



The new labelling will be positioned on top of the nano capsule in a radial manner.

## Affected Products:

Order Code	Product Description
96HICP42EUC11--A	Sartobind Phenyl nano 3 ml, 8 mm, 4 units
96IEXQ42DN-11	Sartobind Q nano 1 mL, 4 mm, 1 unit
96IEXQ42DN-11--A	Sartobind Q nano 1 mL, 4 mm, 4 units
96IEXQ42EUC11--A	Sartobind Q nano 3 ml, 8 mm, 4 units
96IEXS42DN-11	Sartobind S nano 1 mL, 4 mm, 1 unit
96IEXS42DN-11--A	Sartobind S nano 1 mL, 4 mm, 4 units
96IEXS42EUC11--A	Sartobind S nano 3 ml, 8 mm, 4 units
96STPA42DN-11--A	Sartobind STIC PA nano 1 mL, 4 mm, 4 units

## Change Implementation

This change is controlled internally according to our change management procedures and will be managed with full lot traceability.

The new Sartobind® nano design and labelling will be implemented on April 1<sup>st</sup>, 2021. The new design will be available after depletion of stock.

We thank you for your trust and your continuous use of Sartorius products and look forward to assisting you in any request you may have regarding this change.

Sincerely,

  
Fritjof Linz  
Head of Product Management Separation  
Sartorius Stedim Biotech

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