



CHANGE NOTIFICATION REVISION

Issue Date: February 15, 2024

Change Number: CO-01525

Revision History:

Revision	Issue Date	Revision Description
0	March 15, 2023	Original Issue
1	February 15, 2024	<ul style="list-style-type: none">Edit CoC template to reflect current organizational structure to include current Plant Quality Manager and authorized approvers.Notify of the release of the common Regulatory Information Overview for SaniTech® RIGID Polyvinylidene Fluoride Connectors (RIO-00001) and SaniTech® RIGID Polypropylene Connectors (RIO-00002) manufactured in Garden Grove and Beaverton.Clarify the Animal Derived Materials Statement for the SaniTech® RIGID Polypropylene ConnectorsClarifying USP Class VI languageUpdate SaniTech® RIGID PVDF Connectors shelf-life from 40 year to 5 yearsClarify source of variable fields on Certificate of Conformance (CoC)Provide label template example for SaniTech® RIGID Product Lines with source of variable fields explainedProvide label template examples for Furon® Products with source of variable fields explained

Change Type: Documentation Change

Change Level: Level 1 **Change Categorization:** Revision to Emergency Change

Implementation Date: The RIO and Label Templates are effective as of February 15, 2024

Change Approval Required: No Change Approval Required

Change Description:

As previously communicated in March of 2023, the Saint-Gobain Life Sciences' Garden Grove site updated the format and appearance of the Certificate of Conformance (CoC), Certificate of Analysis (CoA) and product labels. The change aligned Garden Grove with the Saint-Gobain Life Sciences templates for certification and labeling. Following this notification, the changes and clarifications as described below have been implemented effective immediately.

At the time of implementation, the Regulatory Information Overview (RIO) referenced in the CoC was not yet available. RIO documents RIO-00001(SaniTech® RIGID Polyvinylidene Fluoride Connectors) and RIO-00002 (SaniTech® RIGID Polypropylene Connectors) are now released and available for download from the Validation & Technical section of the Bioprocess Solutions website (<https://www.biopharm.saint-gobain.com/validation-technical>). As a part of creating the RIO documents, product claims and product stewardship information were verified. When doing this review, the raw material supplier for the polypropylene material used in the SaniTech® RIGID line informed Saint-Gobain that a revision was implemented in 2021 resulting from changing one of their raw material suppliers and assessing the change as one that did not require customer notification. The previous claim was: *Contains bovine derived ingredients*. The current and accurate claim is: *Components derived from animal sources are not used in the manufacture or formulation of this product*. Negotiation of a change notification agreement is currently in progress to prevent the recurrence of a lack of notification from this supplier in the future.

Previous Claim(s)	Current Claim(s)
Sani-Pro Rigid Polypropylene Line: Contains bovine derived ingredients. (Shown on previous CoC version)	Components derived from animal sources are not used in the manufacture or formulation of this product. (Shown in RIO)



CHANGE NOTIFICATION REVISION

The legacy statement for USP Biological Test for Plastics, Class VI claim for the SaniTech® RIGID products only pertains to the raw materials used to manufacture the parts. As such, the claim wording was updated to ensure applicability is clear and the claim information has been moved from the CoC to the RIO.

Previous Claim(s)	Current Claim(s)
Sani-Pro® product line meets the requirements of the USP, Biological Test for Plastics, Class VI. <i>(Shown on CoC)</i>	The raw materials used to manufacture the PVDF and Polypropylene SaniTech® RIGID Connectors meet the requirements of the USP <88>, Biological Test for Plastics, Class VI. <i>(Shown on RIO)</i>

A business decision was made to adjust the shelf-life and expiration dating for the SaniTech® RIGID PVDF line from 40 years to 5 years.

Previous Claim(s)	Current Claim(s)
Shelf-life of 40 years <i>(Shown on RIO)</i>	Shelf-life of 5 years <i>(Shown on RIO)</i>
Expiration Date of 40 years from date of manufacture <i>(Shown on CoC)</i>	Expiration Date of 5 years from date of manufacture <i>(Shown on CoC)</i>

The following updates have been made to the CoC and labeling templates.

- Updated to reflect current organizational structure to include current Plant Quality Manager and authorized approvers

Furthermore, to provide further clarity on the source of the field information shown on the CoC and labeling and to establish a standard label template for SaniTech® RIGID and Furon Products, the following templates and field explanations are provided in Figure 1, 2 and 3 for the source of each field.



CHANGE NOTIFICATION REVISION



Manufacturer:

7301 Orangewood Avenue.,
Garden Grove, CA 92841, USA

Certificate of Conformance

Part Number/ Revision:	<i>Will show Part Number as shown in ERP system Revision: Will show Revision</i>	Customer Part Number/ Revision:	<i>Will show Customer Part Number if Applicable, for Custom Items Only Revision: Customer revision as applicable</i>
Description:	<i>Part Description as shown in ERP system</i>		
Lot Number:	<i>Lot Number as shown in ERP system</i>	Lot Quantity:	<i>Lot Quantity for the entire lot</i>
Date of Manufacture: (DD/MMM/YYYY)	<i>Date of Manufacture</i>	Expiration Date: (DD/MMM/YYYY)	<i>Expiration date for Rigid products</i>
Post Processing Number: (Refer to the attached Certificate for Additional Detail)		<i>Ensure that the Post Processing Number is entered here. If not applicable, "N/A" shall be shown. The information provided in parenthesis must match the document name on the certificate that accompanies the CoC when applicable.</i>	

We certify the material listed above conforms in full with the following specifications:

All items have been manufactured, inspected, tested, and accepted in accordance with our Quality Management System certified to ISO 9001:2015 and AS9100 Rev D. Documentation substantiating this certification is kept on record per the Company's retention policy and is available for review.

All materials and processes used in manufacturing conform to the materials and/or manufacturing specifications and notes indicated on the as applicable purchase order, drawing, specifications, quality assurance requirements, Regulatory Information Overview (RIO), Technical Dossier, other applicable approved documents effective on the date of manufacture.

Saint-Gobain does not warrant the product for any particular application, and it is the responsibility of the user to conduct tests that are deemed necessary to determine the suitability of the product for any particular use. Saint-Gobain's sole responsibility shall be for failure to manufacture the product in accordance with specifications and requirements of the buyer, and from defects in material and workmanship. This warranty is expressly made in lieu of any and all other warranties and Saint-Gobain's sole liability shall be to replace any product not in conformance with the specification and requirements of the buyer.

Site Representative Releasing Product & Date:	<i>Signature of Employee who generated the CoC and the Date the CoC was generated</i>
--	---

The Plant Quality Manager Terry Fender has authorized the above individual to sign this certification for product release.

Figure 1: Garden Grove CoC Field Explanations



CHANGE NOTIFICATION REVISION



Product Code: *Product Code as shown in ERP system*

Description: *Description as shown in ERP system*

Lot Number: *Lot Number as shown in ERP system*

Quantity: *Package Quantity*

Date of Manufacture: *Date of Manufacture*

Saint - Gobain
7301 Orangewood Avenue, Garden Grove, CA 92841 USA

Figure 2: Garden Grove SaniTech ® RIGID Product Lines Label Template with Field Source Explanation



Part number as shown in ERP system

Part #: 

Quantity: *Package Quantity* **Lot #:** *Lot Number as shown in ERP system*

Description: *Description as shown in ERP system*

Made in USA **www.Furon.com** **MFG Date:** *Date of Manufacture*

Figure 3: Garden Grove Furon® Label Template with Field Source Explanation



CHANGE NOTIFICATION REVISION

Products Impacted:

Product Certification: All Life Sciences product produced at Saint-Gobain Garden Grove are in the scope of this change.

Product Labeling: All Life Sciences product produced at Saint-Gobain Garden Grove are in the scope of this change except for:

- Customer directed labelling which is part of Bill of Materials, driven by customer engineering specifications
- Labels applied directly onto Furon® finished product assemblies

Change Rationale:

The original change was implemented in April 2023 to continually improve and to adhere to Saint-Gobain Life Sciences standardizations. This notification revision is being sent to update and provide additional clarity to the changes that were made in the labeling and certification, to communicate the release of RIO Documents RIO-00001 and RIO-00002, and to provide clarity to product claim information.

Change Impact / Risk Assessment:

The following has been evaluated for impact:

- There will be no impact to drawings or specifications.
- There will be no impact to the validated state of the products and associated processes.
- There will be no impact to the manufacturing environments associated with the products in scope of this change.
- There will be no impact to the form, fit or function of the products in scope of this change.
- There will be impact to the certificates and labeling of the product as described below.

Process Element	Comparison	Risk Assigned	Actions to be taken to Mitigate Risk
Product Label	Minor Changes to Format	Low	All Sani-Pro® Rigid and Sani-Tech® Rigid Product Lines Packaging Labels will follow the templates shown above in Figure 2 and Figure 3 respectively
Product Certification	Minor Changes to Format	Low	All Sani-Pro® Rigid and Sani-Tech® Rigid Products and Furon® will follow the templates shown above in Figure 1.
SaniTech® RIGID Product Line Materials of Animal Origin Claim	Updated Statement	Low- material transitioned from containing material of animal origin to being animal derived component free.	Previous Claim: Contains bovine derived ingredients Current Claim: Components derived from animal sources are not used in the manufacture or formulation of this product. Claim updated in RIO provided to customers via this notification. Negotiation of a change notification agreement is currently in progress to prevent the recurrence of a lack of notification from this supplier in the future.
SaniTech® RIGID Product Line USP Biological Reactivity Tests	Clarified Statement	Low – No product change	No change to product claim. Change made to clarify the claim wording for raw material applicability only.
Shelf-Life	Reduced from 40 to 5 years	Low	No risk to product. Recommend customer reviews inventory management. Running change, will only impact shipments after implementation date and will be visible on CoC.



CHANGE NOTIFICATION REVISION

Next Steps:

Please take this opportunity to contact your respective Customer Service Representative or Business Development Manager should you have any questions / concerns.

Terry Fender
Quality Manager
Saint-Gobain Garden Grove

Hannah Hertrick
Product Manager – Filtration and Rigid
Components, Bioprocess Solutions