



## SUPPLIER CHANGE NOTIFICATION

**Issue Date:** June 11, 2024

**Change Number:** DCRR-2024-530-00049 Rev. (0)

**Change Type:** Documentation Change

**Change Level:** Level 1 (High)

**Change Categorization:** Routine 6M notification

**Implementation Date:** December 2024

**Change Approval Required:** Not Applicable.

### Change Description and Rationale:

In an effort to continually improve and standardize our business systems, Saint-Gobain Life Sciences will be updating the Global CoC and CoA templates with the following changes.

- 1) **The Biocompatibility claim statement is changed to become optional when it is applicable to the product being released or required by the end user.**

This statement is not required for all products supplied by Saint-Gobain Life Sciences therefore the change is to make it be an optional field. This will only be visible for products supplied by Saint-Gobain Life Sciences where it is a product defined requirement and currently documented on the certificate.

- 2) **The Biocompatibility claim statement content has changed to align with the product claim change associated with change notification CO-03373.**

The Bioprocess Solutions business has approved a product claim change, CO-03373, specific to the language used to support Biocompatibility. A separate change notification has been supplied to customers that are impacted by the product claim change for additional justification and rationale. This will only be visible for products supplied by Saint-Gobain Life Sciences where it is a requirement.

- 3) **Minor formatting content to add a “,” where required throughout the document.**

The formatting change does not impact any content within the certificate.

- 4) **Removal of the statement under the signature “The Plant Quality Manager (Insert Name) has authorized the above individual to sign this certification for product release” and add “Authorized” in front of the Quality Representative releasing the product.**

This modification has been made to simplify the requirement to assure authorized quality representatives are approving the certificates for product release.

### Scope of Change:

The change to the global Saint-Gobain Life Sciences Certificate of Conformity (CoC) and Certificate of Analysis (CoA) templates applies to all Saint-Gobain Life Sciences sites where the global CoC and CoA have been implemented. Those sites include:

Akron, OH USA (for products as applicable)  
Bangalore, India (for products as applicable)  
Beaverton, MI USA  
Charny, France (for products as applicable)  
Clearwater and Largo, FL USA  
Dublin, Ireland  
Gaithersburg, MD USA  
Garden Grove, CA USA (for products as applicable)

Saint-Gobain Performance Plastics Corporation

31500 Solon Road,  
Solon, OH 44139 USA

CN# DCRR-2024-530-00049

Form: SOP-FLS-CORP-0009 Form 2  
Form Revision: 3

Page 1 of 4  
CONFIDENTIAL AND PROPRIETARY



## SUPPLIER CHANGE NOTIFICATION

Hangzhou, China (for products as applicable)  
SQF, France (for products as applicable)  
Macon, France (for products as applicable)  
Mickleton, NJ USA (for products as applicable)  
Neuhaus, Germany (for products as applicable)  
Neuss, Germany (for products as applicable)  
Plymouth, MN USA  
Poestenkill, NY USA  
Portage, WI USA (for products as applicable)  
Shanghai, China (for products as applicable)  
Suwa, Japan (for products as applicable)  
Taunton, MA USA  
Traverse City, MI USA  
Songdo, South Korea

There is no impact to the product release certificates that do not currently use the global Saint-Gobain Life Sciences template.

### Change Impact / Risk Assessment:

Process Element	Risk Assigned	Actions to be taken to Mitigate Risk
Product Drawings	None	There is no impact.
Product Claims	None	There is no impact.
Product Certifications	Low	All Saint-Gobain Product Certificates of Conformance and Certificates of Analysis will be revised. Refer to Attachment I and Attachment II for samples.

### Next Steps:

These document changes are not retroactive and will only be applied to lots produced after the implementation date of the new templates at the specific sites. The updated CoC and CoA templates will be available for use after **November 30, 2024**.

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

Allison Vereb  
Quality Director, Bioprocess Solutions  
[allison.vereb@saint-gobain.com](mailto:allison.vereb@saint-gobain.com)

### Enclosures:

Attachment I – Revised Certificate of Conformance (CoC) Template Sample  
Attachment II – Revised Certificate of Analysis (CoA) Template Sample



**SUPPLIER CHANGE NOTIFICATION**  
**Attachment I – Revised Certificate of Conformance Example**



**Manufacturer:**  
(Insert the site's address)

**Certificate of Conformance**

<b>Part Number/ Revision:</b>	<i>REQUIRED: Saint-Gobain Number / Revision as shown in QAD</i>	<b>Customer Part Number/ Revision:</b>	<i>Customer Number / Revision as shown in QAD. If not applicable, "N/A" shall be shown.</i>
<b>Description:</b>	<i>REQUIRED: Item Description as shown QAD. Must include material description.</i>		
<b>Lot Number:</b>	<i>REQUIRED: Lot Number</i>	<b>Lot Quantity:</b>	<i>REQUIRED: Lot Quantity</i>
<b>Date of Manufacture:</b> <i>(Place date format here)</i>	<i>REQUIRED: Date of Manufacture</i>	<b>Expiration Date:</b> <i>(Place date format here)</i>	<i>Expiration Date. If not applicable, "N/A" shall be shown.</i>
<b>Post Processing Number:</b> (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:**

<i>All items have been manufactured, inspected, tested, and accepted in accordance with our Quality Management System certified to (Insert ISO certifications that pertain to your site). Documentation substantiating this certification is kept on record per the Company's retention policy and is available for review.</i>	
<i>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, or other applicable approved documents effective on the date of manufacture. The (insert the correct statement: fluid path, ASTM plaques of resin/rubber, assembly, etc.) meets the requirements of the USP&lt;88&gt;, Biological Test for Plastics, Class VI, and/or USP&lt;87&gt;, and/or ISO 10993-5. (This last statement may be removed if not applicable.)</i>	
<i>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.</i>	
<b>Authorized Quality Representative Releasing Product &amp; Date:</b>	<i>Signature of Quality Employee who generated COC and the Date the CoC was generated</i>



## SUPPLIER CHANGE NOTIFICATION

### Attachment II – Revised Certificate of Analysis Example



**Manufacturer:**  
(Insert the site's address)

### Certificate of Analysis

<b>Part Number/ Revision:</b>	<i>REQUIRED: Saint-Gobain Number / Revision as shown in QAD</i>	<b>Customer Part Number/ Revision:</b>	<i>Customer Number / Revision as shown in QAD. If not applicable, "N/A" shall be shown.</i>
<b>Description:</b>	<i>REQUIRED: Item Description as shown QAD. Must include material description.</i>		
<b>Lot Number:</b>	<i>REQUIRED: Lot Number</i>	<b>Lot Quantity:</b>	<i>REQUIRED: Lot Quantity</i>
<b>Date of Manufacture:</b> <i>(Place date format here)</i>	<i>REQUIRED: Date of Manufacture</i>	<b>Expiration Date:</b> <i>(Place date format here)</i>	<i>Expiration Date. If not applicable, "N/A" shall be shown.</i>
<b>Post Processing Number:</b> <i>(Refer to the attached Certificate for Additional Detail)</i>		<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 CoA when applicable.</i>	

Property	Specification	Results	Units
<i>Property</i>	<i>Specification</i>	<i>Results</i>	<i>Units</i>

*Rows may be added as required*

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

<i>All items have been manufactured, inspected, tested, and accepted in accordance with our Quality Management System certified to (Insert ISO certifications that pertain to your site). Documentation substantiating this certification is kept on record per the Company's retention policy and is available for review.</i>	
<i>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, or other applicable approved documents effective on the date of manufacture. The (insert the correct statement: fluid path, ASTM plaques of resin/rubber, assembly, etc.) meets the requirements of the USP&lt;88&gt;, Biological Test for Plastics, Class VI, and/or USP&lt;87&gt;, and/or ISO 10993-5. (This last statement may be removed if not applicable.)</i>	
<i>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.</i>	
<b>Authorized Quality Representative Releasing Product &amp; Date::</b>	<i>Signature of Quality Employee who generated COA and the Date the COA was generated</i>

Form: SOP-FLS-CORP-0040 Form 2  
Revision 5

Page 1 of 1  
Saint-Gobain Proprietary

Saint-Gobain Performance Plastics Corporation

31500 Solon Road,  
Solon, OH 44139 USA

CN# DCRR-2024-530-00049

Form: SOP-FLS-CORP-0009 Form 2  
Form Revision: 3

Page 4 of 4  
CONFIDENTIAL AND PROPRIETARY