SUPPLIER CHANGE NOTIFICATION

Issue Date: 03 September 2024

Change Number: CO-04091 Rev. (0) **Change Type:** Documentation Change

Change Level: Level 2 - Low Risk **Change Categorization:** Routine 3-month Notification

Implementation Date: January 1st, 2025

Change Approval Required: Not Applicable

Change Description:
To continually improve and standardize our business systems, Saint-Gobain Bioprocess Solutions (Saint-Gobain) business will be updating the location in which product specifications (e.g., USP Class VI, Animal Derived Content, Shelf Life, etc.) are documented for custom Single Use Assemblies (SUA) and custom Bioprocess and Cell Therapy (CT) Bags. These claims are currently captured on Page 2 of the Customer Drawing Template.

In the future state, all product claims will be placed on a Product Quality Statements Sheet (PQS) as a separate document from the Customer Drawing. This PQS will require review and approval during the design phase and/or during revisions for SUA and Bioprocess and CT Bags with the Customer Drawing. Refer to Appendix I and II for the current state and the future state.

The PQS will only be created for newly designed SUA as of the implementation date. All existing and approved SUAs product documentation will ***not*** be impacted until the SUA goes through a future design change (Product Revision).

Products Impacted:
The change to the Saint-Gobain Customer Drawing template and the creation of the PQS applies to all Saint-Gobain Bioprocess Solution sites where custom SUA and bags are manufactured. Those sites include:

Bangalore, India
Beaverton, MI USA
Charny, France
Clearwater and Largo, FL USA
Dublin, Ireland
Gaithersburg, MD USA
Hangzhou, China
Plymouth, MN USA
Songdo, South Korea

Change Rationale:
The change is being made to continually improve and standardize Saint-Gobain's business systems as well as streamline elements of the design process.

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Change Impact / Risk Assessment:
This change should not affect a customer's ability to receive or use product and does not involve form, fit, or function. The customer shall receive the same information in a different format, and it will be provided in the same frequency and at the same stage in the design process as previously received.

Process Element	Risk Assigned	Actions to be taken to Mitigate Risk
Customer Drawing	Low	The Claims on Page 2 of the Customer Drawing will be placed on a Product Quality Statements Sheet (PQS) as a separate document from the Customer Drawing. This PQS will require review and approval during the design phase and/or during revisions. Refer to Attachment I for a sample of the current Page 2 Product Claims and Attachment II for a sample Product Quality Statements Sheet (PQS). Page 1 of the drawing will reference the PQS controlled document number.
Product Claims	None	There are no changes to the content or scope of the existing claims for impacted products.
Part Numbers	None	This change will not impact the part numbering for impacted products.
Product Certificates	None	This change will not impact the content or formatting of the product certificates for impacted products.

Next Steps:
These document changes are not retroactive and will only be applied to new designs of SUA/bags or revisions to existing SUA/bags. The PQS will be available for use after January 1st,2025.

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

Brandon Graham
BPS Quality & Compliance Program Manager
Brandon.t.graham@saint-gobain.com

STATEMENTS

This assembly has a Sterility Assurance level SAL 10^-6 per ANSI/AAMI/ISO11137 for fluid path only. Product has been irradiated at 27.5-44 kGy.

The fluid path meets the requirements of the USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5.

The fluid pathway components are either animal derivative content free (ADCF) or compliant with EMA/410/01 Rev.3.

No special storage conditions. Products awaiting shipment are stored in ambient lighting, temperature and humidity conditions.

Ambient storage conditions consist of a cool, dry environment away from direct sunlight at 75°F +/- 20°F, and relative humidity ranges from 10% to 70% in the original, unopened package.

Shelf Life is 3 years from the Date of Manufacture.

Latex is not used in the manufacture of this product and does not come in contact with latex materials during the manufacturing or packaging process.

Fluid extracts from representative product meet USP <788>, Particulate Matter in Injections.

Representative product is tested quarterly per USP <85> and is below the 0.25 EU/mL limit.

CUSTOMER NAME	CUSTOMER NAME HERE	PROJECT NUMBER:	COMPONENTS ARE SUPPLIED PER MANUFACTURER'S SPECIFICATIONS UNLESS OTHERWISED NOTED	TOTAL TUBING LENGTHS ARE **ESTIMATED** REQUIREMENTS	THIRD ANGLE PROJECTION	UNLESS OTHERWISE NOTED: ALL DIMENSIONS ARE INCHES, DUAL DIMENSIONS (MM). TUBING DIMENSIONS TO MFG. SPEC.	0-6.000 (152mm) ±.375(±10 mm); 6.125-12.000 (155mm-304mm) ±.500(±13 mm); 12.125-36.000 (308mm-915mm) ±1.000(±26 mm); 36.125-72.000 (918mm-1829mm) ±2.000(±51 mm); 72.125-120.000 (1831mm-3048mm) ±3.000(±51 mm); >120.000 (>3048mm) ±3%		
CUSTOMER APPROVAL:	***DATE:***	XX-XXXX							
		PATENT:	NOT APPLICABLE			DRAWN BY:XX	DATE:MM/DD/YY	CHKD BY:XX	DATE:MM/DD/YY
PRINTED NAME/TITLE:		PACKAGING	INDIVIDUALLY DOUBLE BAGGED AND LABELED, BULK PACK A/R			APPD BY: XXS	DATE: DD MMM YY	SCALE: NTS	SIZE: C
		PRIMARY MFG SITE:	4451 110th Avenue North Clearwater, FL 33762 Telephone: 727-531-4191 Fax: 727-530-5603						
CONFIDENTIAL AND PROPRIETARY: PROPERTY OF SAINT-GOBAIN PERFORMANCE PLASTICS CORPORATION. ANY REPRODUCTION, DISTRIBUTION AND/OR ANY USE IS PROHIBITED WITHOUT WRITTEN CONSENT FROM SAINT-GOBAIN.		ALTERNATE MFG SITE:							

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DESCRIPTION: DESCRIPTION HERE

PART #: SGXXXXX REV: X

Product Quality Statements

Date:

Part/Drawing #: SGXXXXX **Part Revision:** A **Product Statements #:** PS00001 **Statement Revision:** 1

Purpose: The information below is intended to outline the regulatory information related to the above part. This is meant to be a summation of the requested information and not a complete evaluation of the part.

ISO 13485/ISO 14001

All Items have been manufactured, inspected, tested, and accepted in accordance with our QMS. Product has been manufactured in an ISO 7 cleanroom. Documentation substantiating this certification is kept on record per the Company's retention policy and is available for review.

Storage Requirements

Ambient storage conditions consist of a cool, dry environment away from direct sunlight at 75ºF +/- 20ºF, and relative humidity ranges from 10% to 70% in the original, unopened package.

Quality Assurance Lot Release Criteria

Saint-Gobain conducts release testing to ensure compliance with quality checks, as applicable. The statement of conformance is on the certification (as defined by product requirements) issued for each lot/batch.

Certification

Certificate of Analysis provided with each lot/batch

Gamma Irradiation And Sterilty

The Product has a sterility assurance level (SAL) of 10^-6 in accordance with ANSI/AAMI/ISO 11137 for fluid path only. Product has been irradiated at 25-40 kGy.

Bacterial Endotoxin

Representative product is tested quarterly per USP <85> and is below the 0.25 EU/mL limit.

Sub-Visible Particulates

Fluid extracts from representative product meet USP <788>, Particulate Matter in Injections.

Biocompatibility

The fluid path meets the requirements of the USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5.

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Product Quality Statements

Date:

Part/Drawing #: SGXXXXX **Part Revision:** A **Product Statements #:** PS00001 **Statement Revision:** 1

Additional Claims

Melamine is not intentionally added either into the formulation or during the process to produce Saint-Gobain products based on the information provided by our raw material suppliers.

Nitrosamines are not intentionally added either into the formulation or during the process to produce the fluid pathway of Saint-Gobain products based on the information provided by our raw material suppliers.

The product is not intentionally made of or manufactured with Allergens (as defined by the FDA milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans).

The fluid pathway components have both components that contain animal derived material compliant with EMA 410/01 Rev. 3 and components that are not intentionally made or manufactured with animal derived material.

The product has been evaluated against the CONEG Model Toxics in Packaging Legislation. The product(s) referenced DO NOT CONTAIN intentionally introduced lead, cadmium, mercury, hexavalent chromium, phthalates and PFAS in concentration over 100 ppm by weight. This declaration is based on the raw material information provided by our vendors.

In accordance with the regulation EU 2019/1021 as amended to date, Persistant Organic Pollutants (POP), are not used in the formulation or manufacture of this product.

Conflict minerals, as defined by the US Dodd-Frank Act, are not intentionally added or used to manufacture this product.

	Signature/ Date	Title
APPLICATIONS ENGINEER Prepared by		
CUSTOMER AUTHORIZED REPRESENTATIVE Approved by		
SAINT-GOBAIN QUALITY REPRESENTATIVE Approved by		

SAINT-GOBAIN

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