SAINT-GOBAIN

SUPPLIER CHANGE NOTIFICATION

Issue Date: May 30, 2024

Change Number: CO-03373 Rev. (0)

Change Type: Product Claim Change

Change Level: Level 1 (High)

Change Categorization: Routine 6M notification

Implementation Date: Q4 2024

Change Approval Required: Not Applicable for standard products. As custom products are impacted through future product changes customers will be required to approve at that time.

Change Description:
Saint-Gobain Bioprocess Solutions business is aligning with the industry to move away from unnecessary animal testing and utilizing a risk-based approach for testing to support our product biocompatibility claims. Saint-Gobain's strategy is to perform USP <87> and/or ISO 10993-5 testing for fluid path single use tubing, components, bags and assemblies to support cytotoxicity claims. If the test results are acceptable no further testing will be required. If the test results do not pass the USP <87> and/or ISO 10993-5 criteria, Saint-Gobain may choose to perform USP <88> testing. This testing strategy has a direct impact on our product claims.

Table 1. Claim Change

Pre-Change Claim	Post-Change Claim
USP <88> Class VI	USP <88> Class VI and/or ISO 10993-5 and/or USP <87>

All new single use tubing, components, bags and assemblies will be evaluated for the *in vitro* biological reactivity (e.g., USP <87> and/or 10993-5). Existing product with USP <88> claims will be continued to be supported by existing product test documentation. Future material changes may be supported by USP <87> or ISO 10993-5. The type of changes in scope includes product specification/claim change (Level 1).

Scope of Change:
All Saint-Gobain Bioprocess Solutions branded standard products (e.g., tubing, components, and bags) and all single-use assemblies. Refer to Appendix I.

The product claim change applies to all Saint-Gobain Life Sciences sites which produce the products in scope. Those sites include:

Akron, OH USA
Bangalore, India
Beaverton, MI USA
Charny, France
Clearwater and Largo, FL USA
Dublin, Ireland
Gaithersburg, MD USA
Garden Grove, CA USA
Hangzhou, China
SQF, France
Mickleton, NJ USA
Neuhaus, Germany
Neuss, Germany
Oss, Netherlands
Plymouth, MN USA
Poestenkill, NY USA
Portage, WI USA
Shanghai, China
Suwa, Japan
Taunton, MA USA
Traverse City, MI USA
Songdo, South Korea

Change Rationale:

To support Saint-Gobain's social responsibility and sustainability initiatives the Bioprocess Solutions business is reducing and replacing animal testing on our single use products. The proposed change in testing strategy will still assess the bioreactive toxicity risk of our single-use tubing, components, bags and assemblies, while minimizing the use of animal testing.

Change Impact / Risk Assessment:

Both the USP and ISO industry organizations have recently revised their respective biocompatibility guidance emphasizing a risk-based approach to biocompatibility testing. The USP has a decision flow chart which concludes that USP<88> Class VI testing should be reserved for only the most high-risk applications, like implantable medical device materials. Since Single-Use Systems do not fall into that category, it has been widely proposed by many, including internally at Saint-Gobain, that *in vitro* tests for biocompatibility, like USP<87>, may be used to demonstrate biocompatibility. Single-use tubing, components, bags and assemblies only have transient contact with drug product and have no direct contact with patients. Utilizing the current USP chapter <1031>, *The biocompatibility of materials used in drug containers, medical devices, and implants,* flow chart, Saint-Gobain Bioprocess Solutions single-use tubing, components, bags and assemblies do not come into contact with the body directly, the conclusion is that the biocompatibility requirements are met. Based upon the output of Saint-Gobain's internal risk assessment and overall industry acceptance of ISO 10993-5 and USP <87>, the three tests (USP <88>, USP<87>, and ISO10993-5) are equivalent in demonstrating bioreactivity compliance.

Table 2: Impact Assessment

Process Element	Risk Assigned	Actions to be taken to Mitigate Risk
Product Drawings	None Low	*Tubing, Components & Bags*: There will be no impact. *Assemblies:* There will be impact to page 2 of the product drawings as future changes are made to materials for any of the components involved. The new product claim will be utilized on the page 2 for new and any revision after implementation date. Change notifications will be sent in this situation and a deliverable will be to revise the claim on the page 2 of the drawing at that point in time.
Product Claims	Low	Product claims for bioreactivity will change as outlined in this document. No other product claims will be impacted.
Product Certifications	Low	All Saint-Gobain Product Certificates of Conformance and Certificates of Analysis will be revised to support the claim as outlined in the scope of this document.
BSE/TSE	None	There is no impact to current statements.

Process Element	Risk Assigned	Actions to be taken to Mitigate Risk
Sterility/Irradiation	None	There is no impact to current sterile claims or irradiation certificates and processes.
Production Environments	None	There is no impact to the ISO classification of the production environments.
Form, Fit, and Function	None	There is no impact to form, fit, or function.
Product Documentation	Low	*Regulatory Information Overviews (RIOs)*: There will be no immediate impact to this product documentation as part of the change.
	Low	*Validation Guides*: There will be no immediate impact to this product documentation as part of the change.
	Low	*Technical Dossiers*: These documents will be revised to harmonize the future state claim.
	Low	*Product Datasheets*: These documents will be revised to harmonize the future state claim.
	Low	*Website Content:* Affected claims on the Bioprocess Solutions website will be revised to align with the future state claim.

Additional information:
Beginning in Q2 2024, any products undergoing a raw material change will use USP <87> and/or ISO 10993-5 testing to demonstrate bioreactivity compliance. Current USP <88> Class VI claims for existing products will still be applicable until a product change occurs. Any future product change with an impact to bioreactivity will be managed and communicated in accordance with Saint-Gobain's Change Notification and Communication policy. Any new standard product launched will have the future state claim associated with product documentation. For Saint-Gobain Bioprocess Solutions Single Use standard product lines, the associated bioreactivity data will be included in the either Regulatory Information Overviews (RIOs), Validation Guides, or Technical Dossiers. For Saint-Gobain Bioprocess Solutions existing single use custom assemblies, the associated bioreactivity data will be revised on the product drawings during the next required drawing revision which will require customer approval. The product drawings will not be revised as a result of this change. Refer to details in Table 2. For new single use custom assemblies designed prior to the implementation date in this notification, the legacy claim will not be used and will be replaced with the biocompatibility claim.

Next Steps:
These documentation changes are not retroactive and will only be applied to lots produced after the implementation date of the new templates at all the specific sites. A future change notification will be sent for the CoC and CoA templates and shall be available for use in Q4 2024.

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

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Allison Vereb

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Attachment I – Bioprocess Solutions Products In Scope

Product Type
All Single Use Assemblies including but not limited to: o Bio-Simplex Media Bottle Assembly Systems o Bio-Simplex Erlenmeyer Flask Systems o Bio-Simplex Sampling Manifold Systems o EZ-Top Container Closures
Sani-Tech® o STHT-65 tubing o STHT-C tubing o STHT-R tubing o Ultra-65 tubing o Ultra-C tubing o SPT-50 tubing o SPT-60 tubing o SPT-60L tubing
C-Flex® o 001 tubing o 050 tubing o 072 tubing o 082 tubing o 374 tubing o Ultra tubing o Braided tubing PureFit® SIB o PP SIB o PP Barblocks o PP TC Clamps o PVDF SIB o PVDF Barblocks o PVDF TCL Clamps o PP Dip Tubes o Sterile Connectors
Bioprocess Bags
Tygon®

Product Type
o 3350 Tubing o 2475 IB Tubing o 3370 IB Tubing o PVDF SIB o S3TM E-LFL Tubing
PureFlo® PE Vent Filters
PharmaFluor® FEP Tubing
PharmaPure® Low Spallation Pump Tubing
PharMed® BPT Tubing
SaniPure® BDF Tubing
Sani-Link® Ultra Manifolds
Pure-Flo® o PE o PES o PES Z series o PTFE
Equflow® Flow Tube
Vuelife® C Bag
Vuelife® AC Bag
KryoSure® FEP Bag
Vuelife® HP Bag
Valplus™ Tubing
Zero® Filter