変更のお知らせ（日本語訳）

通知番号：2016-120-00006
2016 年 9 月 27 日

主題：
サンゴバン・グローバルの Certificate of Conformance（CoC）および Certificate of Analysis（CoA）定型書式の改訂

変更の範囲：
この変更は、CoC および CoA のグローバル定型書式を導入している、弊社米国 Taunton 工場で製造・認定されたすべての製品に適用されます。

変更内容および影響評価：
弊社のビジネスシステムを継続して向上および標準化させるという努力の下、以下の変更とともに、CoC および CoA の定型書式を改訂いたします。

- ***「滅菌試験番号：(詳細は滅菌証明書を参照)」*という記載を、*「後処理試験番号：（詳細は添付の証明書を参照)」*に変更します。**
  後処理を行うすべての製品に「滅菌」という表示をするわけではないため、この変更を行います。例えば、製品に「γ 線照射」という表示を行うことは可能ですが、こうしたラベル表示は、製品が処理証明書に記載されている照射線量に暴露された事実を意味するに過ぎません。製品が滅菌状態であることを保証してはいません。製品ラベルに殺菌表示がされておらず、製品の滅菌状態の保証を希望される場合は、弊社担当営業もしくはカスタマーサービスにご連絡いただき、当該サービスのお見積もりについてお問い合わせください。

- **特定の施設が ISO 基準の認定を受けていることを、CoC/CoA に記載します。**
  公認機関による定期的な監査を受け、各製造施設の品質管理システム（QMS）が CoC/CoA に記載された ISO 基準に適合していることを保証するために、この変更を行います。注：FDA に登録し、医療機器を製造している施設のみが、CoC および CoA の 21 CFR 820 に適合します。他の弊社製造工場は、該当する場合、それぞれの ISO 証明書のみを記載します。

- **Regulatory Information Overview（RIO）および改訂情報は、当該工場で RIO が使用されている CoC/CoA に記載します。**
  お客様からご質問の多い規制情報が記載される管理文書を追跡できるよう、この変更を行います。ひとたび各製造工場に RIO を導入すると、QMS の一部に組み込まれます。そのため、QMS 内の他の管理文書と同様に、3 年ごとに定期レビューを受けることになります。

この変更のお知らせにより、製品、製品クレーム、製造方法、試験方法または製品の出荷基準への変更はございません。新しい CoC および CoA の定型書式については、上記の変更概要の例を添付文書 1 および添付文書 2 に示しておりますので、ご参照ください。変更のあった特定の情報については、わかりやすいように赤いハイライトで示しております。

変更実施日：
このフォーマット変更は遡及適用されず、変更実施日以降に製造されたロットにのみ適用されます。改訂された CoC および CoA は、弊社米国 Taunton 工場の弊社施設において、2017 年 1 月 2 日以降に適用開始となります。

今後の対応：
この機会に、できるだけ早期にカスタマーサービス担当者または弊社担当営業にご連絡いただき、追加情報をお求めください。

よろしくお願いいたします。

Mohammad Falaki
米国 Taunton 工場　品質マネージャー

Manufacturer:

700 Warner Blvd.
Taunton, MA 02780 USA

Certificate of Analysis

Part Number/ Revision:	***REQUIRED: Saint-Gobain Number / Rev as shown in QAD***	**Customer Part Number/ Revision:**	*Customer Number / Rev as shown in QAD. If not applicable, "N/A" shall be shown.*
Description:	***REQUIRED: Item Description as shown QAD***		
Lot Number:	***REQUIRED: Lot Number***	**Lot Quantity:**	*REQUIRED: Lot Quantity*
Date of Manufacture: (DD/MMM/YYYY)	***REQUIRED: DOM***	**Expiration Date: (DD/MMM/YYYY)**	*Expiration Date. If not applicable, "N/A" shall be shown.*
Post Processing Run Number: (Refer to the attached Certificate for Additional (Detail)	***NA***		

Property	Specification	Result	Units

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 14001:2004, 9001:2008, ISO 13485:2006, ENISO 13485:2012. 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 purchase order, drawing, specifications, quality assurance requirements, Regulartory Information Overview (RIO) Revision 0, or 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.

Quality Approval:	*Signature of Quality Employee generating the COA.*	**Date:**	*DD/MMM/YYYY*

Manufacturer:

700 Warner Blvd.
Taunton, MA 02780 USA

Certificate of Conformance

Part Number/ Revision:	*REQUIRED: Saint-Gobain Number / Rev as shown in QAD*	**Customer Part Number/ Revision:**	*Customer Number / Rev as shown in QAD. If not applicable, "N/A" shall be shown.*
Description:	*REQUIRED: Item Description as shown QAD*		
Lot Number:	*REQUIRED: Lot Number*	**Lot Quantity:**	*REQUIRED: Lot Quantity*
Date of Manufacture: (DD/MMM/YYYY)	*REQUIRED: DOM*	**Expiration Date: (DD/MMM/YYYY)**	*Expiration Date. If not applicable, "N/A" shall be shown.*
Post Processing Run Number: (Refer to the attached Certificate for Additional Detail)	*NA*		

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 14001:2004, 9001:2008, ISO 13485:2006, ENISO: 13485:2012.. 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 purchase order, drawing, specifications, quality assurance requirements, Regulatory Information Overview (RIO) Revision 0, or 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.

Quality Approval:	*Signature of Quality Employee generating the COC.*	**Date:**	*DD/MMM/YYYY*

添付文書 1—よくある質問

CoC と CoA の違いは？
適合証明書 Certificate of Conformance（CoC）は生産ロットが所定の手順、規格に従い生産されたことを証明するものです。分析証明書 Certificate of Analysis（CoA）はそれに加え、当該ロットの試験条件、試験結果を追記したものになります。

Description の欄には何が記載されますか？
説明欄には、サンゴバン統合基幹業務システム（ERP）に含まれる、製品の簡単な説明が記載されます。ERP システムに入力できる文字数は限られているため、この記述は略記されていることがあります。

Lot Quantity の欄には何が記載されますか？
ロット量の欄には、製造される製品の総量が入力されます。例えば、お客様から 5 つの製品をご注文いただき、弊社が総量 10 の製品ロットを生産した場合、証明書に記載される量は 10 となります。

使用期限の欄に「該当なし」の選択肢があるのはなぜですか？
使用期限のない製品は「該当なし」となります。使用期限がある製品の場合、当該欄には日／月／年の形式で使用期限が表示されます。（例：08-Dec-2014）

CoC または CoA に、発注番号、販売注文番号または配送番号が記載されないのはなぜですか？
使用する CoC/CoA の書式を標準化するため、発注番号、販売注文番号または配送番号は表示されません。その代わりに、こうした情報は納品書または出荷通知といった書類に記載することが可能です。

CoC または CoA に、検査計画が記載されないのはなぜですか？
製品の検査および出荷に用いた検査計画は、CoC および CoA が新しい書式になっても変更されません。製造施設で現在使用している検査計画は今後も引き続き使用しますが、証明書には記載されません。特定の製造工場の検査計画に関する詳細情報は、カスタマーサービス担当者または弊社担当営業にお問い合わせください。

CoC または CoA に製品の適合性または特性評価が記載されないのはなぜですか？
（BSE/TSE や USP の記載、滅菌表示等を含みますがこれに限定されるものではありません）
原材料の形状、適合性および製品の機能に変更はありません。定型書式を標準化するため、製品の具体的な情報は証明書には記載されません。その代わりに、製品の具体的情報は製品図面や仕様書、Regulatory Information Overview （RIO）、バリデーション・ガイド、製品の MSDS、製品パンフレットなど他の所定の書類や、弊社ウェブサイト等に記載しております。

Notice of Change

Notification Number: 2016-120-00006
September 27, 2016

Subject:
Update to the Saint-Gobain Global Certificate of Conformance (C of C) and Certificate of Analysis (C of A) templates

Scope:
This change applies to all product manufactured and certified at Taunton, MA. Saint-Gobain sites where the global C of C and C of A templates have been implemented:

Change Description and Impact Assessment:
In an effort to continually improve and standardize our business systems, Saint-Gobain will be updating the Global C of C and C of A template with the following changes:

- **The statement *"Sterilization Run Number: (Refer to Sterilization Certificate for Additional Detail)"* will now be changed to *"Post Processing Run Number: (Refer to the attached Certificate for Additional Detail).***
  This change is being made since not all products that see Post Processing are label claimed as 'sterile'. Example, product may be label claimed as 'gamma-irradiated.' This type of label claim simply means the product has been exposed to the irradiation dose range indicated on the certificate of processing. It does not guarantee that the product is sterile. If the product label does not contain a sterile claim and you would like the assurance that the product is sterile, then please contact your local customer service department at the manufacturing site to provide a quote for such a service.

- **The ISO standard that the specific site is certified to will be referenced in the C of C /C of A**
  This change is being made to provide assurance that each manufacturing site's Quality Management System (QMS) is being routinely audited by a notified body for conformance to the ISO standard(s) indicated on the C of C/C of A. NOTE: Only sites registered with the FDA and manufacturing medical devices will include compliance to 21 CFR 820 on the C of C and C of A. All other FLS sites will only list their respective ISO certification(s) where applicable.

- **The Regulatory Information Overview (RIO) and revision information will be referenced in the C of C/C of A where the RIO is in use at that site**
  This change is being made to provide traceability to the controlled document that contains regulatory information frequently requested by customers. The RIO is part of the QMS once implemented by each site. As such, it will be routinely reviewed every three years like any other controlled document within the QMS.

Please note that as a result of this change notice there has not been any changes to the products, product claims, manufacturing process, testing methods, or product release criteria. The updated C of C and C of A template formats can be seen in Attachment 1 and Attachment 2 to illustrate the changes outlined above. The specific information being changed is highlighted in red for clarity.

Implementation Date:

The format change is not retroactive and will only be applied to lots produced after the implementation date. The updated C of C and C of A will be available for use at Taunton, Saint-Gobain starting January 2, 2017

Next Steps:
Please take this opportunity to contact your Customer Service Representative or your Saint-Gobain District Sales Manager with any additional information requirements at your earliest convenience.

Kind Regards,

Mohammad Falaki
Plant Quality Manager

Manufacturer:

700 Warner Blvd.
Taunton, MA 02780 USA

Certificate of Analysis

Part Number/ Revision:	***REQUIRED: Saint-Gobain Number / Rev as shown in QAD***	**Customer Part Number/ Revision:**	*Customer Number / Rev as shown in QAD. If not applicable, "N/A" shall be shown.*
Description:	***REQUIRED: Item Description as shown QAD***		
Lot Number:	***REQUIRED: Lot Number***	**Lot Quantity:**	*REQUIRED: Lot Quantity*
Date of Manufacture: (DD/MMM/YYYY)	***REQUIRED: DOM***	**Expiration Date: (DD/MMM/YYYY)**	*Expiration Date. If not applicable, "N/A" shall be shown.*
Post Processing Run Number: (Refer to the attached Certificate for Additional (Detail)	***NA***		

Property	Specification	Result	Units

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 14001:2004, 9001:2008, ISO 13485:2006, ENISO 13485:2012. 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 purchase order, drawing, specifications, quality assurance requirements, Regulartory Information Overview (RIO) Revision 0, or 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.

Quality Approval:	*Signature of Quality Employee generating the COA.*	**Date:**	*DD/MMM/YYYY*

Manufacturer:

700 Warner Blvd.
Taunton, MA 02780 USA

Certificate of Conformance

Part Number/ Revision:	*REQUIRED: Saint-Gobain Number / Rev as shown in QAD*	**Customer Part Number/ Revision:**	*Customer Number / Rev as shown in QAD. If not applicable, "N/A" shall be shown.*
Description:	*REQUIRED: Item Description as shown QAD*		
Lot Number:	*REQUIRED: Lot Number*	**Lot Quantity:**	*REQUIRED: Lot Quantity*
Date of Manufacture: (DD/MMM/YYYY)	*REQUIRED: DOM*	**Expiration Date: (DD/MMM/YYYY)**	*Expiration Date. If not applicable, "N/A" shall be shown.*
Post Processing Run Number: (Refer to the attached Certificate for Additional Detail)	*NA*		

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 14001:2004, 9001:2008, ISO 13485:2006, ENISO: 13485:2012.. 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 purchase order, drawing, specifications, quality assurance requirements, Regulatory Information Overview (RIO) Revision 0, or 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.

Quality Approval:	*Signature of Quality Employee generating the COC.*	**Date:**	*DD/MMM/YYYY*

Attachment 1- Frequently Asked Questions

What is the difference between the CoC and the CoA?
The Certificate of Conformance (CoC) is a document that states the lot of product has been manufactured in accordance with approved procedures and specifications. The Certificate of Analysis (CoA) states the same but includes specific test conditions and test results for the lot of product being certified.

What will the Description field say?
The Description field is the brief narrative of the product contained in the Saint Gobain Enterprise Resource Planning system (ERP). The description may be abbreviated since the ERP system has character count limits.

What will the Lot Quantity field say?
The Lot Quantity field displays the entire quantity of the product being manufactured. For example, if the customer orders 5 widgets and Saint Gobain produced a lot of product containing a total quantity of 10, then the Certificate will display a quantity of 10.

Why is N/A an option for the Expiration Date field?
Product which does not have an expiration date will show N/A. If the product does have an expiration date, the field will display the expiration date in the format of DD/MMM/YYYY (example: 08-Dec-2014).

Why doesn't the CoC or CoA show my Purchase Order Number, Sales Order Number, or Delivery Number?
To standardize the CoC/CoA formats used, the Purchase Order Number, Sales Order Number, or Delivery Number will not be shown. Rather, this information may be shown on items such as the Packing Slip or Shipping Notice.

Why doesn't the CoC or CoA describe the Inspection Plan used?
The inspection plan used to inspect and release the product remains unchanged as a result of the new CoC and CoA template. The approved inspection plan currently used at the manufacturing site will continue to be used, but will not be displayed on the certificates. Additional information on the specific site inspection plan may be obtained from your Customer Service Representative or Saint-Gobain District Sales Manager.

Why aren't the product compliance or characterization claims displayed on the CoC or CoA?
(Including but not limited to: BSE/TSE statement, USP statements, Sterilization Claims, etc.).
The materials form, fit, and function of product remain unchanged. In order to standardize the template, product specific information will not be shown on the certificates. Rather, product specific information can be obtained in other approved documents such as product drawings/specifications, Regulatory Information Overview (RIO), Validation Guides, Product MSDS, Product Brochures, as well as the Saint-Gobain's website.