



お取引先様各位

2015年5月19日
サンゴバン株式会社
機能樹脂事業部

Certificate of Conformance (CoC), Certificate of Analysis (CoA)

フォーマット変更のお知らせ

平素は格別のご高配を賜り、厚く御礼申し上げます。
さて、首記の件につきまして、以下のとおりご連絡申し上げます。

敬具

記

弊社米国フロリダ州クリアウォーター工場より輸入している下記製品につきまして、CoC、CoAのフォーマットが変更になりますのでご連絡致します。
いずれ全ての工場発行分について、同様の書式となるよう予定しており、詳細は追ってご連絡致しますが、手始めとして、クリアウォーター工場製造分のものから変更開始となります。

- ※ このラベル変更による生産工程、試験方法、出荷基準、製品の性能自体への変更はございません。
- ※ すでに CoC、CoA フォーマットを記載した仕様書につきましては、本文書を以って変更の通知に代えさせていただきますが、仕様書の変更が必要な場合はご連絡下さい。

対象製品 : BIO-SIMPLEX® CELL CULTURE LABORATORY ASSEMBLIES
 BIO-SIMPLEX® MANIFOLDS
 BIO-SIMPLEX® MOLDED SAMPLING SYSTEMS w/ CONTAINERS
 C-FLEX® TUBING
 C-FLEX® TUBING - BRAIDED
 C-FLEX® ULTRA
 C-FLEX® MOLDED PRODUCTS (BIO-SIMPLEX, EZ TOPS)
 EZ-TOP® - CONTAINER CLOSURES - C-FLEX®

変更時期 : 2015 年 6 月 1 日製造分より
お問い合わせ先 : 弊社カスタマーサービス(042-352-21029)まで
 詳細は別紙和訳・英文をご参照下さい。

以上

(CN# 2014-032_J)

別紙-1 FAQ 抜粋

1. CoC と CoA の違いは？

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。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。基本的には CoC となります。

2. 従来のフォーマットには適合規格(BSE/TSE、USP 等)の情報の記載があったのにそれが記載されなくなった理由は？

製品自体の性能に変更はございません。適合規格等製品固有の情報につきましては、仕様書、バリデーション、SDS、カタログ、ウェブサイト等に記載しております。ご不明な点がございましたら、弊社カスタマーサービスまでお申し付け下さい。



Manufacturer:
Site Specific Address
City, State Zip code Country

Certificate of Conformance

Part Number/ Revision:	<i>REQUIRED: Saint-Gobain Number / Rev</i>	Customer Part Number/ Revision:	<i>Customer Number / Rev. If not applicable, "N/A" shall show.</i>
Description:	<i>REQUIRED: Item Description as shown QAD</i>		
Lot Number:	<i>REQUIRED: Lot Number</i>	Lot Quantity:	<i>REQUIRED: Lot Quantity</i>
Date of Manufacture: (DD/MMM/YYYY)	<i>REQUIRED: DOM</i>	Expiration Date: (DD/MMM/YYYY)	<i>Expiration Date. If not applicable, "N/A" shall show.</i>
Sterilization Run Number: (Refer to Sterilization Certificate for Additional Detail)		<i>Sterilization Run Number. If not applicable, "N/A" shall be shown.</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. Documentation substantiating this certification is kept on record per the Company's retention policy and are 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 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:	<i>Employee generated COC.</i>	Date:	<i>Date COC was generated. DD/MMM/YYYY</i>
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Manufacturer:
Site Specific Address
City, State Zip code Country

Certificate of Analysis

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

Property	Specification	Result	Units

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

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Quality Approval:	<i>Employee name that generated COC.</i>	Date:	<i>Date COC was generated. DD/MMM/YYYY</i>
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