



変更通知（和訳）

変更通知：18140-014

2018年7月11日

件名：Certificate of Conformance および Certificate of Analysis の書式変更

お客様各位

お客様により良いソリューションをお届けし、サンゴバン パフォーマンスプラスティックスの複数の拠点から購入されるお客様にさらに一貫したエクスペリエンスをご提供するために、サンゴバン パフォーマンスプラスティックスのビーバートン工場（米国 ミシガン州）では、2019年1月7日以降に製造される製品に添付する Certificate of Conformance および Certificate of Analysis の様式をグローバル版に移行します。

新しい様式には、必要に応じて部品番号、ロット番号、品目、数量、製造日、使用期限および後処理情報等の必要な情報が記載されます。図面ごとにお客様の仕様に適合していることの認証も記載されますが、現行の様式とは異なり、それぞれの個別要件は記載されません。お客様の特別な要件または仕様は、部品の図面またはその他の仕様書にご記載いただく必要があります。

ご参考までに、本通知に現行の様式と新しい様式のサンプルを添付しております。ご確認いただき、ご質問がございましたら弊社カスタマーサービス担当者までご連絡ください。

以上

VanBennek
om, Julie A

Digitally signed by VanBennekom, Julie A
DN: dc=net, dc=atcsg, dc=if, dc=zh,
ou=CUS, ou=BU-PPL, ou=US0016,
ou=Users, cn=VanBennekom, Julie A,
email=Julie.A.VanBennekom@saint-
gobain.com
Date: 2018.07.11 16:51:58 -04'00'

Julie VanBennekom
Quality Assurance Manager
Saint-Gobain Performance Plastics

添付書類 A から D：Certificate of Conformance および Certificate of Analysis のサンプル

添付書類 A : サンゴバン パフォーマンスプラスティックス (ビーバートン工場) の現行
Certificate of Conformance の様式サンプル



Saint-Gobain Performance Plastics Corporation
3910 Terry-Diane Street • Beaverton, Michigan • 48612 • USA • Tel: (989) 435-9533 • Fax: (989) 435-2355

Certificate of Compliance

PART NUMBER: F01234	CUSTOMER PART NUMBER: ABCDE
PO NUMBER: 987654321	DESCRIPTION: <Part Description>
SG SALES ORDER NUMBER: 12345678	QUANTITY: 9999
LOT/BATCH NUMBER: 87645321	DATE OF MANUFACTURE: MM/DD/YYYY

WE CERTIFY THE MATERIAL LISTED ABOVE COMPLIES IN FULL WITH THE FOLLOWING SPECIFICATIONS:

-THE COMPONENTS/MATERIALS USED IN THE PRODUCTION OF THE PRODUCT ABOVE WERE
MANUFACTURED IN A MANNER COMPLIANT WITH CURRENT GOOD MANUFACTURING PRACTICES
-THIS PRODUCT IS MANUFACTURED IN THE U.S.A.
-SHELF LIFE: 5 YEARS FROM DATE OF MANUFACTURE
-MEETS OR EXCEEDS USP CLASS VI, USP 88 CLASS VI AND USP 87 REQUIREMENTS, CURRENT
REVISION
-THIS MATERIAL IS NOT INTENDED FOR INVASIVE USE
-The materials used in the manufacture of this product that come in contact with the fluid pathway are either
animal derivative content free or compliant as defined in specification EMEA 410.01 Rev.3.

WE CERTIFY THAT ALL ITEMS ON YOUR PURCHASE ORDER HAVE BEEN MANUFACTURED, INSPECTED, TESTED AND ACCEPTED IN ACCORDANCE WITH OUR
INSPECTION SYSTEM.

WE ALSO CERTIFY THAT ALL MATERIALS AND MANUFACTURING 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 ENGINEERING DOCUMENTS.

TEST REPORTS SUBSTANTIATING THIS CERTIFICATION ARE KEPT ON RECORD IN THE COMPANY'S QC FILE AND ARE AVAILABLE FOR REVIEW.

SAINT-GOBAIN PPL 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

Created by: Jeff Smith

2018-06-30 02:34:33
DATE

添付書類 B : サンゴバン パフォーマンスプラスティックス (ビーバートン工場) の現行
Certificate of Analysis の様式サンプル

 SAINT-GOBAIN Saint-Gobain Performance Plastics Corporation 3910 Terry-Diane Street • Beaverton, Michigan • 48612 • USA • Tel: (989) 435-9533 • Fax: (989) 435-2355			
Certificate of Analysis			
<table border="1"><tr><td>PART NUMBER: FA4231 PO NUMBER: 987654 SG SALES ORDER NUMBER: 12345678 LOT/BATCH NUMBER: 00000000</td><td>CUSTOMER PART NUMBER: ABC123 DESCRIPTION: <Part Description> QUANTITY: 9999 DATE OF MANUFACTURE: MM/DD/YYYY</td></tr></table>		PART NUMBER: FA4231 PO NUMBER: 987654 SG SALES ORDER NUMBER: 12345678 LOT/BATCH NUMBER: 00000000	CUSTOMER PART NUMBER: ABC123 DESCRIPTION: <Part Description> QUANTITY: 9999 DATE OF MANUFACTURE: MM/DD/YYYY
PART NUMBER: FA4231 PO NUMBER: 987654 SG SALES ORDER NUMBER: 12345678 LOT/BATCH NUMBER: 00000000	CUSTOMER PART NUMBER: ABC123 DESCRIPTION: <Part Description> QUANTITY: 9999 DATE OF MANUFACTURE: MM/DD/YYYY		
WE CERTIFY THE MATERIAL LISTED ABOVE COMPLIES IN FULL WITH THE FOLLOWING SPECIFICATIONS:			
<table border="1"><tr><td><ul style="list-style-type: none">-THE COMPONENTS/MATERIALS USED IN THE PRODUCTION OF THE PRODUCT ABOVE WERE MANUFACTURED IN A MANNER COMPLIANT WITH CURRENT GOOD MANUFACTURING PRACTICES-THIS PRODUCT IS MANUFACTURED IN THE U.S.A.-MEETS OR EXCEEDS USP CLASS VI, USP 88 CLASS VI AND USP 87 REQUIREMENTS, CURRENT REVISION-SILICONE PRODUCTS ARE COMPLIANT TO THE EXTRACTABLE LIMITS SPECIFIED IN FDA 21 CFR 177.2600, RUBBER ARTICLES INTENDED FOR REPEATED USE, PARAGRAPHS (d), (e), AND (f).-THIS MATERIAL IS NOT INTENDED FOR INVASIVE USE-STERILITY SHELF LIFE: 3 YEARS FROM THE DATE OF MANUFACTURE-PRODUCT EXPOSED TO GAMMA RADIATION WITH IN 25-40 kGy SPECIFICATION-The materials used in the manufacture of this product that come in contact with the fluid pathway are either animal derivative content free or compliant as defined in specification EMEA 410.01 Rev.3.</td></tr></table>		<ul style="list-style-type: none">-THE COMPONENTS/MATERIALS USED IN THE PRODUCTION OF THE PRODUCT ABOVE WERE MANUFACTURED IN A MANNER COMPLIANT WITH CURRENT GOOD MANUFACTURING PRACTICES-THIS PRODUCT IS MANUFACTURED IN THE U.S.A.-MEETS OR EXCEEDS USP CLASS VI, USP 88 CLASS VI AND USP 87 REQUIREMENTS, CURRENT REVISION-SILICONE PRODUCTS ARE COMPLIANT TO THE EXTRACTABLE LIMITS SPECIFIED IN FDA 21 CFR 177.2600, RUBBER ARTICLES INTENDED FOR REPEATED USE, PARAGRAPHS (d), (e), AND (f).-THIS MATERIAL IS NOT INTENDED FOR INVASIVE USE-STERILITY SHELF LIFE: 3 YEARS FROM THE DATE OF MANUFACTURE-PRODUCT EXPOSED TO GAMMA RADIATION WITH IN 25-40 kGy SPECIFICATION-The materials used in the manufacture of this product that come in contact with the fluid pathway are either animal derivative content free or compliant as defined in specification EMEA 410.01 Rev.3.	
<ul style="list-style-type: none">-THE COMPONENTS/MATERIALS USED IN THE PRODUCTION OF THE PRODUCT ABOVE WERE MANUFACTURED IN A MANNER COMPLIANT WITH CURRENT GOOD MANUFACTURING PRACTICES-THIS PRODUCT IS MANUFACTURED IN THE U.S.A.-MEETS OR EXCEEDS USP CLASS VI, USP 88 CLASS VI AND USP 87 REQUIREMENTS, CURRENT REVISION-SILICONE PRODUCTS ARE COMPLIANT TO THE EXTRACTABLE LIMITS SPECIFIED IN FDA 21 CFR 177.2600, RUBBER ARTICLES INTENDED FOR REPEATED USE, PARAGRAPHS (d), (e), AND (f).-THIS MATERIAL IS NOT INTENDED FOR INVASIVE USE-STERILITY SHELF LIFE: 3 YEARS FROM THE DATE OF MANUFACTURE-PRODUCT EXPOSED TO GAMMA RADIATION WITH IN 25-40 kGy SPECIFICATION-The materials used in the manufacture of this product that come in contact with the fluid pathway are either animal derivative content free or compliant as defined in specification EMEA 410.01 Rev.3.			
<table border="1"><tr><td><Measured characteristics and post-processing data entered here></td></tr></table>		<Measured characteristics and post-processing data entered here>	
<Measured characteristics and post-processing data entered here>			
<p>WE CERTIFY THAT ALL ITEMS ON YOUR PURCHASE ORDER HAVE BEEN MANUFACTURED, INSPECTED, TESTED AND ACCEPTED IN ACCORDANCE WITH OUR INSPECTION SYSTEM.</p> <p>WE ALSO CERTIFY THAT ALL MATERIALS AND MANUFACTURING 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 ENGINEERING DOCUMENTS.</p> <p>TEST REPORTS SUBSTANTIATING THIS CERTIFICATION ARE KEPT ON RECORD IN THE COMPANY'S QC FILE AND ARE AVAILABLE FOR REVIEW.</p> <p>SAINT-GOBAIN PPL 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.</p>			
Quality Approval	2018-05-02 09:22:03 DATE		
Created by: Debbie Willford			

添付書類 C : サンゴバン パフォーマンスプラスティックス (ビーバートン工場) の新しい Certificate of Conformance の様式サンプル (2019年1月7日製造分からこの Certificate of Conformance に置き換わります)



Manufacturer:

Saint-Gobain Performance Plastics Corporation
3910 Terry-Diane Street • Beaverton, Michigan • 48612 • USA • Tel: (989) 435-9533 • Fax: (989) 435-2355

Certificate of Conformance

Part Number/ Revision:	<i>REQUIRED: Saint-Gobain Number / Revision</i>	Customer Part Number/ Revision:	<i>Customer Number / Revision. If not applicable, "N/A" shall be shown.</i>
Description:	<i>REQUIRED: Item Description.</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>
Post Processing Run Number: (Refer to the attached Certificate of Processing for Additional Detail)		<i>Post Processing Run Number is entered here. If not applicable, "N/A" shall be shown. An example of a post processing run would be gamma irradiator run number.</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 certified to ISO 13485:2016. 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 <X>, 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, Biological Test for Plastics, Class VI. *(USP Class VI statement is omitted if not applicable)*

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>Signature of Quality Employee who generated COC.</i>	Date:	<i>Date COC was generated. DD/MMM/YYYY</i>
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添付書類 D : サンゴバン パフォーマンスプラスティックス (ビーバートン工場) の新しい Certificate of Analysis の様式サンプル (2019 年 1 月 7 日製造分からこの Certificate of Analysis に置き換わります)



Saint-Gobain Performance Plastics Corporation
3910 Terry-Diane Street• Beaverton, Michigan• 48612• USA• Tel: (989) 435-9533• Fax: (989) 435-2355

Certificate of Analysis

Part Number/ Revision:	REQUIRED: Saint-Gobain Number / Revision	Customer Part Number/ Revision:	Customer Number / Revision. If not applicable, "N/A" shall be shown.
Description:	REQUIRED: Item Description as shown QAD. Must include material description.		
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 of Processing for Additional Detail)		Post Processing Run Number is entered here. If not applicable, "N/A" shall be shown. An example of a post processing run would be gamma irradiator run number.	

Property	Specification	Results	Units

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Quality Approval:	Signature of Quality Employee who generated COA	Date:	Date COA was generated. DD/MMM/YYYY
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