

a Garlock Hygienic Technologies company

26 Brookfield Drive • Sparta, NJ 07871 Tel: 973-579-2959 • Toll Free: 866-442-2959 Fax: 973-579-7275 • <a href="www.rubberfab.com">www.rubberfab.com</a>

Platinum Silicone Spore Trap Thermocouple

Liner Design 1 Platinum Silicone Class VI

Liner Design 3 Platinum Silicone Class VI

Platinum Silicone V2B Screen Gasket

Tri-Clamp Platinum Silicone, Perforated Sock Gasket

Clear Platinum Silicone Camlock Sock Screen

Platinum Silicone Thermocouple

## **Change Notification**

Dear Valued Customer,

1. General Information

This Change Notice letter is provided to inform you of the changes to products you may have purchased from us.

Date Issued:	06-26-2020	06-26-2020		
Subject:	Platinum Cured	Platinum Cured Silicone certification to include USP 87 & 88		
Change Notificatio	n Number: 20-06	20-06		
Effective Date:	08-10-2020	08-10-2020		
2. Type of Change				
☐ Drawing Change				
☐ Material Change				
□ Documentation Change				
□ Certification Change □				
☐ Packaging/Labeling Change				
3. Products Affected (xxx denotes variable characters)				
Item Series	Description	Item Series	Description	
40GGI-PX-XXX				
42GGI-PX-XXX	Platinum Silicone Gauge Guard Isolator Gasket	42RXPX-100-HH	1in Mini Platinum Silicone HAT Gasket	
40RXPX-XXX		42TCC-PX-050/075	.5/.75in Platinum Silicone Tri Clamp Cap (GGP style)	
42RXPX-XXX	Platinum Silicone Tri-Clamp Gasket	42TCC-PX-050/075-L	(includes LONG)	
40RXPX-BI-XXX	Platinum Silicone Biologic Indicator Tri-Clamp		4in Platinum Silicone/316L SS Vertical Orifice Plate	
42RXPX-BI-XXX	Gasket	A40RXPX-400-VER	Tri-Clamp Gasket	
	2in Platinum Silicone Diffuser Gasket, 2		Platinum Silicone SS Orifice TC Gasket (includes	
40RXPX-D-200-2M	Micron	A80RXPX-XXX	electropolish and standard finish or gasket only)	

#### 4. Reason for Change:

40RXPX-F-XXX

40RXPXPXXX

40RXPXSXXX

42RXPXSXXX

40RXPX-V-F-XXX

SNAPTITE-RXPX-XXX

40TCC-PX-XXX

To comply with customer requested certification requirements for inclusion of USP Chapter 87 & 88 testing on certificate of compliance where applicable. We have conducted additional USP material testing and can now offer this additional certification.

G-SPR-XXX

G-TH-XXX

LINERS-D1-RXPX

LINERS-D3-RXPX

SSG-CAM-PX-L-XXX

PSG-PX-XXX

SSG-PX-XXX

V2B-RXPX-XXX

#### 5. Description of Change:

Certificate of Compliance statements to be updated to include U.S.P. Chapter <87> and <88>, Class VI-121 degrees C. Current certificates only state USP Class VI.

Change product label conformance certification from Passed U.S.P. Class VI Testing to USP 87, 88 Class VI and USP 87, 88 CLASS VI, 3A. Sample certificates and labels are included to illustrate the changes.

Should you have any questions regarding this notice, please contact your Customer Service Representative at 1-866-442-2959. Thank you for your continued support of Rubber Fab, a Garlock Hygienic Technologies Company.

Sean Mayer

Sean Mayer, Quality Assurance Manager Date: 06-26-2020

Platinum Silicone Tri-Clamp Gasket, Flanged

Platinum Silicone Perforated Plate Tri-Clamp

Platinum Silicone Screen Tri-Clamp Gasket

Platinum Silicone Tri Clamp Cap Gasket

Platinum Silicone Tri-Clamp Gasket, Flanged,

Platinum Silicone Snap Tite Gasket, 80 Duro

Gasket, 316SS

Schedule 5 (6" & 8" sizes)

Form: RFQP103-F1 Change Notification Number: 20-06 Page 1 of 1



# **CERTIFICATE OF COMPLIANCE**

## U.S.P. CLASS VI

Rubber Fab, a Garlock Hygienic Technologies company certifies that the material from which we manufacture the below mentioned parts has passed U.S.P. Class VI Cytotoxicity testing and meets 3A and USDA standards and are BSE/TSE compliant. Elastomer parts are FDA CFR 21, 177.2600 compliant, and PTFE, FEP, PFA and Tuf-Steel parts are FDA CFR 21, 177.1550 compliant. Rubber Fab certifies the material for the below mentioned part is Phthalate Free. Note: Electropolished products are 15RA or better

**Customer Name:** Sample Cert represents all sizes

Customer's PO No.: Sample

Part No.: Part Number

Part Description: Platinum Silicone Gasket

Material: Platinum Cured Silicone

**Lot Number:** Sample Lot

Cure Date: 00/00

CERTIFIED

Certified By:

A PRES

Sean Mayer, Quality Assurance

Sean Mayor

Date: Month/DD/YYYY



The material used to manufacture our EPDM, FKM Fluoroelastomer, Silicone, PTFE, and Tuf-Steel® parts is Animal-Derived Ingredient-Free.

#### Garlock Hygienic Technologies, LLC

d/b/a Rubber Fab, a Garlock Hygienic Technologies company 26 Brookfield Drive, Sparta, New Jersey 07871 \* Tel: (973) 579-2959 \* Fax: (973) 579-7275

www.rubberfab.com



# **CERTIFICATE OF COMPLIANCE**

**USP 87, 88 CLASS VI, 3A** 

Rubber Fab, a Garlock Hygienic Technologies company certifies that the material from which we manufacture the below mentioned part has passed U.S.P. Chapter <87> and <88>, Class VI-121 degrees C., Cytotoxicity testing, meets 3A and USDA standards, and is BSE/TSE compliant. Elastomer parts are FDA CFR 21, 177.2600 compliant, and PTFE and Tuf-Steel parts are FDA CFR 21, 177.1550 compliant. Rubber Fab certifies the material for the below mentioned part is Phthalate Free. Note: Electropolished products are 15RA or better and standard parts are 20RA or better for stainless steel product contact surfaces.

**Customer Name:** Sample Cert represents all sizes

**Customer's PO No.:** Sample

Part No.: Part Number

**Part Description:** Platinum Silicone Gasket

Material: Platinum Cured Silicone

**Lot Number:** Sample Lot

**Cure Date:** 00/00

CERTIFIED

Certified By:

AD.

Sean Mayer, Quality Assurance

Sean Mayor

Date: Month /DD/YYYY



The material used to manufacture our EPDM, FKM Fluoroelastomer, Silicone, PTFE, and Tuf-Steel® parts is Animal-Derived Ingredient-Free.

Garlock Hygienic Technologies, LLC

d/b/a Rubber Fab, a Garlock Hygienic Technologies company 26 Brookfield Drive, Sparta, New Jersey 07871 \* Tel: (973) 579-2959 \* Fax: (973) 579-7275

www.rubberfab.com

# Rubber Fab

a Garlock Hygienic Technologies company

### Change Notice 20-06 Label Samples

# **Rubber Fab**

a Garlock Hygienic Technologies company

Rubber Fab a Gartock Hygienic Technologies company

ITEM NO.:

DESCRIPTION:

MATERIAL: Platinum Cured Silicone

ITEM NO.:

DESCRIPTION:

MATERIAL: Platinum Cured Silicone

Quantity: LOT#; DOM:

**FDA Compliant** 

USP 87, 88 CLASS VI

New Label

ITEM NO .:

DESCRIPTION:

MATERIAL: Platinum Cured Silicone

Quantity: LOT#: DOM:

FDA Compliant

Passed U.S.P. Class VI Testing

Current LabeL



FDA Compliant

USP 87, 88 CLASS VI, 3A

