

Change Notification

Dear Valued Customer,

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

1. General Information			
Date Issued:	05-13-2020		
Subject:	Black FKM Fluoroelastomer gasket certification to include USP 87 & 88		
Change Notification Number:	20-05		
Effective Date:	06-15-2020		
2. Type of Change			
<input type="checkbox"/> Drawing Change <input type="checkbox"/> Material Change <input checked="" type="checkbox"/> Documentation Change <input checked="" type="checkbox"/> Certification Change <input checked="" type="checkbox"/> Packaging/Labeling Change			
3. Products Affected			
Item Series	Description	Item Series	Description
40IV-150, -200, -250, -300, -400	Black FKM Fluoroelastomer I-Line Gasket (1.5" through 4" Sizes only, excludes 1", 6" and 8")	40MOFSFY-XXX	Black FKM Fluoroelastomer Tri-Clamp Gasket, Flanged (6" – 12" sizes)
40MPSFY-XXX	Black FKM Fluoroelastomer Tri-Clamp Gasket	DIN32676-XXX-FKM	FKM; Tri-Clamp Gasket, DIN32676, DIN11850, DIN10357
40MPFSFY-XXX	Black FKM Fluoroelastomer Tri-Clamp Gasket, Flanged	ISO1127-XXX-FKM	FKM; Tri-Clamp Gasket, ISO1127
40MOSFY-XXX	Black FKM Fluoroelastomer Tri-Clamp Gasket (6"-12" sizes)	ISO2852-XXX-FKM	FKM; Tri-Clamp Gasket, ISO2852
4. Reason for Change:			
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.			
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, Quality Assurance Manager

Date: 05-13-2020

Rubber Fab

a Garlock Hygienic Technologies company

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 are 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.

Customer Name: Sample Cert represents all sizes
Customer's PO No.: Sample
Part No.: Part Number
Part Description: Black FKM Fluoroelastomer Gasket

Material: FKM Fluoroelastomer
Lot Number: Sample Lot
Cure Date: 00/00

C E R T I F I E D



Certified By:

Sean Mayer, *Quality Assurance*

Date: MM/DD/YYYY



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

Gaskets * Hose * Hose Assemblies * Tubing * Fittings * Pump and Replacement Parts

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

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CERTIFICATE OF COMPLIANCE

U.S.P. CLASS VI

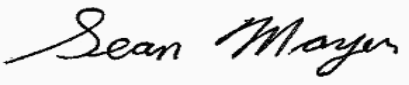
Rubber Fab, a Garlock Hygienic Technologies company certifies that the material from which we manufacture the below mentioned parts has passed U.S.P. Class VI Cytotoxicity testing and meets 3A and USDA standards and are BSE/TSE compliant. Elastomer parts are FDA CFR 21, 177.2600 compliant, and PTFE, 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

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Customer's PO No.: Sample
Part No.: Part Number
Part Description: Black FKM Fluoroelastomer Gasket

Material: FKM Fluoroelastomer
Lot Number: Sample Lot
Cure Date: 00/00

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USP 87, 88 CLASS VI

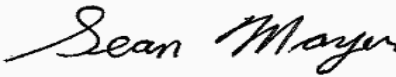
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Customer's PO No.: Sample
Part No.: Part Number
Part Description: Black FKM Fluoroelastomer Gasket

Material: FKM Fluoroelastomer
Lot Number: Sample Lot
Cure Date: 00/00

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Sean Mayer, *Quality Assurance*

Date: MM/DD/YYYY



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CERTIFICATE OF COMPLIANCE

USP 87, 88 CLASS VI, 3A

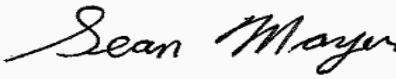
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Change Notice 20-05 Label Samples

Rubber Fab

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ITEM NO.:

DESCRIPTION:

MATERIAL:
FKM Fluoroelastomer

Quantity:
LOT#:
DOM:

FDA Compliant
USP 87, 88 CLASS VI, 3A



New Label

Rubber Fab

a Garlock Hygienic Technologies company

ITEM NO.:

DESCRIPTION:

MATERIAL:
FKM Fluoroelastomer

Quantity:
LOT#:
DOM:

FDA Compliant
USP 87, 88 CLASS VI



New Label

Rubber Fab

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ITEM NO.:

DESCRIPTION:

MATERIAL:
FKM Fluoroelastomer

Quantity:
LOT#:
DOM:

FDA Compliant
Passed U.S.P. Class VI Testing



Current Label