

Rubber Fab

a Garlock Hygienic Technologies company

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To
Rubber Fab / PSI Products Partners in Europe

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2019-11-26

GHT RF Europe - Product Change Notification - 04 - 2019 – Additional manufacturing site Silicone CPO-3003/80

| | |
|--|---|
| 1. General Information | |
| Date Issued: | 11-21-2019 |
| Subject: | Platinum Silicone Second Manufacturing Source CPO-3003/80 |
| Change Notification Number: | 19-04 |
| Effective Date: | 12-26-2019 |
| 2. Type of Change | |
| <input type="checkbox"/> Drawing Change | |
| <input type="checkbox"/> Material Change | |
| <input type="checkbox"/> Documentation Change | |
| <input type="checkbox"/> Certification Change | |
| <input type="checkbox"/> Packaging/Labeling Change | |
| <input checked="" type="checkbox"/> Other Change (Additional manufacturing site) | |
| 3. Products Affected | |
| P/N: 42RXPX-050 Description: .50in Platinum Silicone Tri-Clamp® Gasket | |
| P/N: 42RXPX-075 Description: .75in Platinum Silicone Tri-Clamp® Gasket | |
| P/N: 40RXPX-100 Description: 1in Platinum Silicone Tri-Clamp® Gasket | |
| P/N: 40RXPX-150 Description: 1.5in Platinum Silicone Tri-Clamp® Gasket | |
| 4. Reason for Change: | |
| Due to increased demand of platinum silicone gaskets using compound CPO-3003/80. | |
| 5. Description of Change: | |
| A second source contract manufacturing supplier has been qualified by Rubber Fab to supplement molding of our platinum silicone Tri-Clamp® gaskets in 4 sizes mentioned above. | |
| This product will be made of the same silicone compound designated as Rubber Fab CPO-3003/80 as our current source. This change will have no impact on the form, fit, function or the quality of gaskets provided. | |
| The compound continues to meet the following compliance: | |
| · Traceability to raw materials and manufacturing site by lot number | |
| · FDA 21 CFR 177.2600 | |
| · USP 87 | |
| · USP 88, Class VI @ 121°C extraction for one hour | |
| · 3-A Sanitary Standard 18-03 | |
| · Animal Derived Ingredient Free (TSE / BSE Safe) | |

Best regards,

Christoph Neuffer
Rubber Fab - Application Engineer

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