

To
Rubber Fab / PSI Products Partners in Europe

Your contact person

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Change Notification - 2021 - 02 – RFSB hose change

Dear valued Business Partner,


we hereby inform you about recent changes we were forced to make concerning the Silicone Hose "RFSB" from Rubber Fab Sparta further described in the following.

Please find specific details on page 2 of this document in the Quality Management Form "*FB 2202 Products Change Notification*"

Best regards,
Team Rubber Fab Europe


Attachments


- PSI Products "FB 2202 Products Change Notification" on page 2
- Sample Certificate RFSB Hose: RF_Sample_Certificate_RFSB_Hose_210616

Area of application: Sales / Anwendungsbereich: Vertrieb	Quality Management Form / Formblatt	
Chapter: 7.5 ISO Kap.: 7.5 ISO	FB 2202 Products Change Notification / Hinweis zu Produktänderungen	Page 1 of 1 / Seite 1 von 1

1. Type of Change / Art der Änderung
<input checked="" type="checkbox"/> Material change <input checked="" type="checkbox"/> Documentation Change <input checked="" type="checkbox"/> Certification Change <input checked="" type="checkbox"/> Additional manufacturing site
2. Products Affected / betroffene Produkte
RFSB Hose Series – Smoothbore Platinum Cured Silicone Hose with Braid Reinforcement Part numbers: 04RFSB, 06RFSB, 08RFSB, 10RFSB, 12RFSB, 16RFSB
3. Reason for Change / Grund der Änderung
<p>Due to reduced availability of our existing supply of RFSB hose, Rubber Fab has approved an alternate second approved source for the material. Review of compliance standards indicates we can add reference to USP chapter 87 & 88, 3-A 18-03 and USDA standards applicable to both sources on Certificate of Compliance statements.</p>
4. Description of Change / Beschreibung der Änderung
<p>This change is valid with immediate effect.</p> <p>Material change: A new compound is also used for this hose, resulting in a change in the hardness of the hose, from the former 70 durometers we are now at 80 durometers Shore hardness. The appearance of the lay line, braid, weave tightness are different from historic material. This will not affect the form, fit or function of the hose.</p> <p>The lot numbers will provide us with the ability to trace it back to the source.</p> <p>Documentation and Certification change: Our RFSB hose continues to maintain the following compliance:</p> <ul style="list-style-type: none"> • Traceability to raw materials and manufacturing site by lot number • FDA 21 CFR 177.2600 • USP 87 & USP 88 (Class VI) • 3-A Sanitary Standard 18-03 • Animal Derived Ingredient Free (TSE / BSE Safe) <p>The Certificate of Compliance shall be updated to include reference to USP chapters 87 & 88, 3-A Sanitary Standard 18-03 and USDA compliance.</p> <p>Additional manufacturing site: A second source supplier has been qualified by Rubber Fab to supplement our RFSB hose.</p> <p>Product dimensions will remain the same and are in this way not affected by the change. Please also note that the RFSB-EU Hose is not affected by this change.</p>

erstellt: Asja Nudl	Geprüft&freigegeben: Birgit Haaser	geändert:	GHT_RF_Europe_PCN_2021_02_RFS B_hose_change_210616
Datum: 23.03.2021	Datum: 25.03.2021	Datum:	

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Your contact person / Ihr Kontakt	Attachments / Anlagen
Christoph Neuffer Rubber Fab – Application Engineer Mail cneuffer@rubberfab.com Phone +49 176 56668135	Sample certificate: RF_Sample_Certificate_RFSD_Hose_210616
Date / Datum	Signature / Unterschrift
16.06.2021	

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