

SGS INSTITUT FRESENIUS GmbH · Postfach 1261 · 65220 Taunusstein

Order no.:3067433

Client:10127213

Dr. Nadine Paul / tp

t +49 6128 744 - 107

f +49 6128 744 - 534

nadine.paul@sgs.com

Consumer Testing Services

Non Food

SGS INSTITUT FRESENIUS GmbH

Im Maisel 14

D-65232 Taunusstein

Taunusstein, 05/AUG/2014

Your order : Testing of silicone
 Your reference : Dirk Bartelmann
 Order date : 11/JUL/2014
 Sample no. : 140786715
 Test period : 15/JUL/2014 – 29/JUL/2014

Test report no.: 3067433-01
Testing according to FDA

Dear Mr. Bartelmann,

Following your request we have tested the sample received on July 14, 2014 according to 21 CFR (Code of Federal Regulation) of FDA (Food and Drug Administration) § 177.2600.

Sample no.	Sample designation
140786715	O-rings 41x4 Silicone 70 red Material-No.: 1370-19002

Detailed results are given on the following page(s).

Assessment:

The sample meets the requirements of 21 CR FDA § 177.2600.

Yours sincerely,

SGS INSTITUT FRESENIUS GmbH



i. V. Dr. Nadine Paul
(Team leader)



i. A. Zamien Sarkardeh
(Project Manager)

Order no. : 3067433
Test report no. : 3067433-01
Sample no. : 140786715

05/AUG/2014

page 2 of 3

Photo documentation:



Order no. : 3067433
 Test report no. : 3067433-01
 Sample no. : 140786715

05/AUG/2014

page 3 of 3

Test results:


FDA 21 CFR § 177.2600 (e) and (f)

1. Extractables

The material was extracted under the below mentioned conditions. The extractives have been determined gravimetrically.

solvent/extraction conditions		Result [mg/in ²]	Requirement [mg/in ²]
Water	first 7 hours	<1	max. 20
	following 2 hours	<1	max. 1
n-Hexane	first 7 hours	16	max. 175
	following 2 hours	< 1	max. 4

SGS INSTITUT FRESENIUS GmbH


 i. V. Dr. Nadine Paul
 (Team leader)


 i. A. Zamien Sarkardeh
 (Project Manager)