Test Report No. 64.165.21.05128.01C Rev.00 Dated 2021-09-23





TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch TÜV SÜD Group

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SUMMARY OF TEST RESULTS

No.	Test Requested	Conclusion	Remarks
1.	For material: Rubber - Test for compliance with U.S. F.D.A. C.F.R. 21. Part 177.2600	PASS	1





1. TESTED SUBJECT DESCRIPTION

Sample Number	Tested Material Description	Photo
001	Blue silicone	





2. TEST RESULT

2.1. TEST FOR COMPLIANCE WITH U.S. F.D.A. C.F.R. 21. PART 177.2600

Test Item	Result(s) [mg/in²]	CFR Specification [mg/in²]	
Test Item	Sample 001		
Total extractive of distilled water at reflux temperature			
- for first 7 hours	< 1.0	< 20	
- for succeeding 2 hours	< 0.1	< 1	
Total extractive of n-hexane at reflux temperature			
- for first 7 hours	5.3	< 175	
- for succeeding 2 hours	< 0.1	< 4	

Note :

- "°F" denotes degree Fahrenheit
- "mg/in²" denotes milligram per square inch
- "<" denotes less than</p>
- Specification is quoted from U.S. F.D.A. C.F.R. 21. Part 177.2600

3. REMARK

The chemical testing was performed in TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch Chemical lab and the test results were reviewed at TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch.

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