



Test Report No. 70.400.23.3265.01-00.01

Rev.00

Dated 2023-12-21

Applicant: Yumi Intelligent Manufacturing (Hangzhou) Co., Ltd

Address: NO.18 ZHENSHAN ROAD, CHANGKOU TOWN, FUYANG,
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Attn.: Zhang Pu

Sample Description: PETG-HYPER (ULTA SPEED PETG)

Model No.: 1.75MM

Country of origin: China

Exported to: U. S. A / EUROPE

Sample Received Date: 2023-12-12

Test Period: From 2023-12-12 to 2023-12-20

Purpose of examination: As specified by client, to test as regulated by the
- U.S. F.D.A. C.F.R. 21

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

Prepared by:

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Designated Reviewer

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Disclaimer Measurement Uncertainty: Unless otherwise agreed upon, pass or fail verdicts are given based on the measured values without consideration of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO IEC 17025 requirements. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as pass or fail.

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SUMMARY OF TEST RESULTS

No.	Test Requested	Conclusion	Remarks
1.	For material: Resinous and polymeric coatings - Test for compliance with U.S. F.D.A. C.F.R. 21. Part 175.300	PASS	

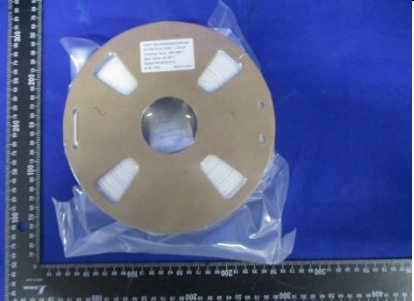


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1. TESTED SUBJECT DESCRIPTION

Sample Number	Tested Material Description	Photo
001	White ST-PETG-HYPER (High Speed PETG)	



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2. TEST RESULT

2.1. TEST FOR COMPLIANCE WITH U.S. F.D.A. C.F.R. 21. PART 175.300

Test Item	Result [mg/in ²]	CFR Specification [mg/in ²]
	Sample 001	
Net chloroform-soluble extractives in distilled water (120°F for 24 hours)	< 1.0	≤ 18
Net chloroform-soluble extractives in 8% ethanol (120°F for 24 hours)	< 1.0	≤ 18
Net chloroform-soluble extractives in n-Heptane (70°F for 30 minutes)	< 1.0	≤ 18

Note :

- “mg/in²” denotes milligram per square inch
- “°F” denotes degree Fahrenheit
- “<” denotes less than
- “≤” denotes not more than
- The specification is quoted from U.S. F.D.A. C.F.R. 21. Part 175.300

APPENDIX I:

Additional models:

1.75MM/2.85MM/3.0MM

Remark :

1. The report covers material testing on specified samples
2. The tested materials covered by the report were declared by the manufacturer to be used on the above models listed

-----End of Report-----

