

# Test Report

No.: ESZ2306120168T00302RM1

Date: Nov. 28, 2023

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**Applicant** : Hoshine Silicon(Jiaxing) Industry Co., Ltd.  
**Address** : Room 202, 2nd Floor NO.530,YASHAN WEST RD.,ZHAPU TOWN,PINGHU CITY,  
ZHEJIANG PROVINCE, P.R OF CHINA

The sample and sample information tested below are provided and confirmed by the applicant

**Sample Name** : Silicone Rubber  
**Model** : Please refer to sample description  
**Received Date** : Jun. 12, 2023  
**Test Period** : Jun. 12, 2023~Jun. 19, 2023  
**Test Summary** :

Test Item	Conclusion
US FDA 21 CFR 177.2600 - Extractable Content	Pass

Remark: Pass: meet the requirement; Fail: Doesn't meet the requirement; N/A: Without conclusions or provide test results only.

Signed for and on behalf of  
EMTEK(Suzhou) Co., Ltd



Prepared by:

Chen Ying, Joyce  
Assistant engineer

Reviewed by:

Zhao Xuwen, Cony  
Technical supervisor

Approved by:

Yuan Qi, Mickey  
Authorized signatory  
Nov. 28, 2023

Test results are only responsible for delivered samples. This test report is issued by the company and is intended for your exclusive use. This test report includes all of the testes requested by you and the results thereof based upon the information that you provided. You have 30 days from data of issuance of this test report to notify us of any error or omission caused by our negligence. A failure to raise such issue within the prescribed time shall constitute your unqualified acceptance of the completeness of this report, the tests conducted and the correctness of the report contents.



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**Sample Description (The sample and sample information tested below are provided and confirmed by the applicant)**

Sample No.	Sample Number	Supplier	Description
03	E2306120168-03	Hoshine Silicon(Jiaxing) Industry Co., Ltd.	Milky white translucent

Model					
No.	External model	No.	External model	No.	External model
1	HS-1131	57	HS-5370PT	113	HS-3472C
2	HS-1141	58	HS-5380PT	114	HS-3482C
3	HS-1151	59	HS-5630	115	HS-5770
4	HS-1161	60	HS-5650	116	HS-5570
5	HS-1171	61	HS-5670	117	HS-3141
6	HS-1175	62	HS-5242G	118	HS-3151
7	HS-1181	63	HS-5252G	119	HS-3161
8	HS-1241	64	HS-5262G	120	HS-7140
9	HS-1251	65	HS-5272G	121	HS-7160
10	HS-1261	66	HS-5282G	122	HS-5350QY
11	HS-1271	67	HS-5242T	123	HSLs-2134BT
12	HS-1281	68	HS-5252T	124	HSLs-2139
13	HS-2041	69	HS-5262T	125	HSLs-2121BW
14	HS-2051	70	HS-5272T	126	HSLs-2131M
15	HS-2061	71	HS-5282T	127	HSLs-2131S
16	HS-2071	72	HS-1140PT	128	HSLs-2141M
17	HS-2111	73	HS-1150PT	129	HSLs-2141F
18	HS-2115	74	HS-1160PT	130	HSLs-2144BT
19	HS-2121	75	HS-1170PT	131	HSLs-2149
20	HS-2122	76	HS-1180PT	132	HSLs-2151S
21	HS-2131	77	HS-1142PT	133	HSLs-2159M
22	HS-2141	78	HS-1152PT	134	HSLs-2154BT
23	HS-2151	79	HS-1162PT	135	HSLs-2154
24	HS-2161	80	HS-1172PT	136	HSLs-2151MD

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Model					
No.	External model	No.	External model	No.	External model
25	HS-2171	81	HS-1182PT	137	HSLs-2151W
26	HS-2171HX	82	HS-1141PT	138	HSLs-2151F
27	HS-2181	83	HS-1151PT	139	HSLs-2164BT
28	HS-2631	84	HS-1161PT	140	HSLs-2164
29	HS-2641	85	HS-1171PT	141	HSLs-2161MD
30	HS-2651	86	HS-1181PT	142	HSLs-2161M
31	HS-2661	87	HS-1540PT	143	HSLs-2161F
32	HS-2671	88	HS-1550PT	144	HSLs-2169
33	HS-3421	89	HS-1560PT	145	HSLs-2174
34	HS-3431	90	HS-1570PT	146	HSLs-2179
35	HS-3441	91	HS-1580PT	147	HSLs-2141
36	HS-3451	92	HS-1542PT	148	HSLs-2149G
37	HS-3461	93	HS-1552PT	149	HSLs-2151
38	HS-3471	94	HS-1562PT	150	HSLs-2151D
39	HS-3481	95	HS-1572PT	151	HSLs-2162
40	HS-3491	96	HS-1582PT	152	HSLs-2161
41	HS-5240	97	HS-5332	153	HSLs-2171
42	HS-5250	98	HS-5342	154	HSLs-2121
43	HS-5260	99	HS-5352	155	HSLs-2129W-F
44	HS-5270	100	HS-5362	156	HSLs-2131
45	HS-5280	101	HS-5372	157	HSLs-2151M
46	HS-5320	102	HS-5382	158	HSLs-2159
47	HS-5330	103	HS-2132	159	HSLs-2179W
48	HS-5340	104	HS-2155S	160	HSLs-2170G
49	HS-5350	105	HS-2440	161	HSLs-2181
50	HS-5360	106	HS-2152	162	HSLs-2171W
51	HS-5370	107	HS-2162	163	HSLs-2141D
52	HS-5380	108	HS-2172	164	HSLs-2171G

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Model					
No.	External model	No.	External model	No.	External model
53	HS-5330PT	109	HS-3432C	165	HSLs-2141W
54	HS-5340PT	110	HS-3442C	166	HSLs-2161S
55	HS-5350PT	111	HS-3452C	167	HSLs-2161W
56	HS-5360PT	112	HS-3462C	168	HSLs-2121M
/	/	/	/	169	HSLs-2141S
170	HS-1532PT	172	HS-1552PT	174	HS-1572PT
171	HS-1542PT	173	HS-1562PT	175	HS-1582PT

## Summary of Test Results

### 1. US FDA 21 CFR 177.2600-Extractable Content

#### 1.1 Test Method: US FDA 21 CFR 177.2600

#### 1.2 Test Result:

Test Item	Unit	Result	Limit	Conclusion
		E2306120168-03		
DI Water Extractable Content (Reflux 7h )	mg/in <sup>2</sup>	0.12	≤ 20	Pass
DI Water Extractable Content (Then Reflux 2h )	mg/in <sup>2</sup>	< 0.1	≤ 1	Pass
N-hexane Extractable content ( Reflux 7h)	mg/in <sup>2</sup>	9.75	≤ 175	Pass
N-hexane Extractable content (Then Reflux 2h )	mg/in <sup>2</sup>	0.63	≤ 4	Pass

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## Sample Photo



### Declaration:

Report ESZ2306120168T00302R was repealed and replaced by report ESZ2306120168T00302RM1.

\*\*\* End of Report \*\*\*

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## 声明 Statement

- 1.本检测报告首页所列信息中除样品来源、接样日期、检测日期、检测结果和检测结论外，均由委托方提供，委托方对样品的代表性和资料的真实性负责，本实验室不承担任何相关责任。  
The information as listed on the first page of this test report was all provided by the client except the sample from, date received, test period, test results and test conclusion. The client shall be responsible for the representativeness of sample and authenticity of materials, for which EMTEK shall bear no responsibilities.
- 2.本检测报告以实测值进行符合性判定，未考虑不确定度所带来的风险，特别约定、标准或规范中有明确规定的除外。此种判定方式所带来的风险由客户自行承担，本实验室不承担相关责任。  
The judgment method of determining the conformity in this test report is according to the measured value without considering the risk caused by uncertainty, unless otherwise clearly stipulated in special agreement, standard or specification. The client shall assume the risk caused by the judgment method, and EMTEK shall not bear related responsibilities.
3. 检测报告无批准人签字及“检验检测专用章”无效，未经本实验室书面同意，不得整体或部分复制本报告。  
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- 4.本检测报告的检测结果仅对送测样品负责，未加盖资质认定标志的检测报告不对社会具有公证证明作用，对于检测数据、结果的使用，所产生的直接或间接损失及一切法律后果，本实验室不承担任何经济和法律后果。  
This test data is only responsible for the tested sample. The data and results provided by the report without CMA accreditation are not to prove to the society, and EMTEK is not responsible for any economic and legal responsibility for the use of the test data, the direct or indirect losses resulting from the use of the test and all legal consequences.
- 5.本检测报告中检测项目标注有下划线则该项目不在本实验室资质认定能力范围内，该项目检测结果仅作为客户委托、科研、教学或内部质量控制等目的使用。  
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- 6.其它声明请查阅报告页脚及书面报告背页。  
For other statements, please refer to the footer of the report.

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## 签发测试报告条款 Conditions of Issuance of Test Reports

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In the event of the improper use of the report as determined by the Company, the Company reserves the right to withdraw it, and to adopt any other additional remedies which may be appropriate.
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Samples submitted for testing are accepted on the understanding that the Report issued cannot form the basis of, or be the instrument for, any legal action against the Company.
6. 如因使用本公司中心任何报告内的资料，或任何传播信息所描述与之有关的测试或研究导致的任何损失或损害，本公司概不负责。  
The Company will not be liable for or accept responsibility for any loss or damage how ever arising from the use of information contained in any of its Reports or in any communication whatsoever about its said tests or investigations.
7. 若需要在法院审理程序或者仲裁过程中使用测试报告，客户必须在提交测试样品前将该意图告知本公司。  
Clients wishing to use the Report in court proceedings or arbitration shall inform the Company to that effect prior to submitting the sample for testing.
8. 该测试报告的支持数据和信息本公司保存 10 年。个别评审机构有特别要求的，检测数据和报告的保存期可依情况变动。一旦超过上述提交的保存期限，数据和信息将被处理掉。任何情况下，本公司不必提供任何被处理的过期数据或信息。即使本公司事先被告知可能会发生相关的损害，本公司在任何情况下也不必承担任何损害，包括（但不限于）补偿性赔偿、利润损失、数据丢失、或任何形式的特殊损害、附带损害、间接损害、从属损害或任何违反约定、违反承诺、侵权（包括疏忽）、产品责任或其他原因的惩罚性损害。  
Subject to the variable length of retention time for test data and report stored hereinto as otherwise specifically required by individual accreditation authorities, the Company will only keep the supporting test data and information of the test report for a period of ten years. The data and information will be disposed of after the aforementioned retention period has elapsed. Under no circumstances shall we provide any data and information which has been disposed of after retention period. Under no circumstances shall we be liable for damage of any kind, including (but not limited to) compensatory damages, lost profits, lost data, or any form of special, incidental, indirect, consequential or punitive damages of any kind, whether based on breach of contract of warranty, tort (including negligence), product liability or otherwise, even if we are informed in advance of the possibility of such damages.





# Certificate of Compliance

No. HXT240411250141

**Applicant** : Wenzhou Songkang Electronic Technology Co., Ltd.  
**Address** : No.2 Fenglian Road, Zhenglou Standard Factory, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang Province  
**Manufacturer** : Wenzhou Songkang Electronic Technology Co., Ltd.  
**Address** : No.2 Fenglian Road, Zhenglou Standard Factory, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang Province  
**Product** : Rhinitis instrument  
**Model(s)** : A1  
**Trademark** : N/A  
**Test Standard(s)** : EN IEC 55014-1: 2021;  
EN IEC 55014-2: 2021.

The EUT described above has been tested by us with the listed standards and found in compliance with the Council EMC Directive 2014/30/EU. It is possible to use CE marking to demonstrate the compliance with the EMC Directive.

The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the test report number: HXT240411250141.



Shenzhen HuaXu Testing Technology Co., Ltd.

106, building B12, Yintian Industrial Zone, Yantian community, Xixiang street, Bao'an District, Shenzhen

HOTLINE:0755-28268723 Email: huaxujiance\_prc@163.com Http:www.hxt-lab.com



# Supplier's Declaration Of Conformity

No. HXT241111251979

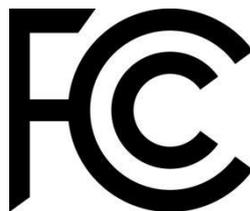
**Applicant** : Wenzhou Songkang Electronic Technology Co., Ltd.  
**Address** : No.2 Fenglian Road, Zhenglou Standard Factory, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang Province  
**Manufacturer** : Wenzhou Songkang Electronic Technology Co., Ltd.  
**Address** : No.2 Fenglian Road, Zhenglou Standard Factory, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang Province  
**Product** : Rhinitis instrument  
**Model(s)** : A1  
**Trademark** : N/A  
**Test Standard(s)** : **FCC Part 15 Subpart B**

This device complies with Part 15 of the FCC rules, operation is subject to the following two conditions:

- (1) This device may not cause harmful interference
- (2) This device must accept any interference received, including interference that may cause undesired operation.

This is the results of test that was carried out by Shenzhen HuaXu Testing Technology Co., Ltd. From the submitted type samples of the product is conformity with the specification of the respective standards.

It is only valid in connection with the test report number: HXT241111251979.



Shenzhen HuaXu Testing Technology Co., Ltd.

106, building B12, Yintian Industrial Zone, Yantian community, Xixiang street, Bao'an District, Shenzhen

HOTLINE:0755-28268723 Email: huaxujiance\_prc@163.com Http:www.hxt-lab.com



# Certificate of Compliance

**No. HXT250211250071**

**Applicant** : Wenzhou Songkang Electronic Technology Co., Ltd.  
**Address** : No.2 Fenglian Road, Zhenglou Standard Factory, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang Province  
**Manufacturer** : Wenzhou Songkang Electronic Technology Co., Ltd.  
**Address** : No.2 Fenglian Road, Zhenglou Standard Factory, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang Province  
**Product** : Rhinitis instrument  
**Model(s)** : A1  
**Trademark** : N/A  
**Test Standard(s)** : IEC 62321-1: 2013, IEC 62321-2: 2013, IEC 62321-3-1: 2013, IEC 62321-5: 2013, IEC 62321-4:2013+AMD1:2017, IEC 62321-6: 2015, IEC 62321-7-1:2015, IEC 62321-7-2: 2017, IEC 62321-8: 2017.

The EUT described above has been examined by us with the listed standards and found in compliance with the Council RoHS Directive 2011/65/EU & (EU)2015/863. It is possible to use RoHS marking to demonstrate the compliance with the RoHS Directive.

The test data obtained and the report issued by laboratories other than HuaXu are provided by the applicant to us for data consolidation purpose. The report shall not be reproduced in part without written approval of us. It is only valid in connection with the test report number: HXT250211250071.



# RoHS



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HOTLINE:0755-28268723 Email: huaxujiance\_prc@163.com Http:www.hxt-lab.com