

检测报告

Detection Report

报告编号:



Certificate No.

425030953

委托单位:
Customer

苏州远赞智造科技有限公司
Suzhou Yuanzan Intelligent Manufacturing Technology Co., Ltd.

受检单位:
Customer

苏州远赞智造科技有限公司
Suzhou Yuanzan Intelligent Manufacturing Technology Co., Ltd.

单位地址:
Address

苏州市昆山市千灯镇圣祥东路188号A1、A5厂房
Building A1 and A5, No. 188 Shengxiang East Road, Qiandeng Town,
Kunshan City, Suzhou City

受检区域:
Detected Area

洁净室
Clean Room

接收日期:
Date of Receipt

2025 - 09 - 21

检测日期:
Date of Detection

2025 - 09 - 21 至 2025 - 09 - 23

微谱检测(苏州)有限公司
WEIPU TESTING TECHNOLOGY (SUZHOU) CO., LTD.



批准人:
Approved by

袁志伟

核验员:
Checked by

谢鹏飞

检测员:
Detected by

谭祎鹏

签发日期:
Date of Issue

2025 - 09 - 30



地址: 苏州市工业园区唯新路58号东区8栋
Address: Building 8, East District, No. 58 Weixin Road, Industrial Park, Suzhou

电话(Tel): 400-700-8005
网址: www.weipugroup.com



本次检测所依据的技术规范:

Reference technical specification to the detection

GB/T 16292-2010 《医药工业洁净室(区)悬浮粒子的测试方法》

Test method for airborne particles in clean room (zone) of the pharmaceutical industry

GB 50591-2010 《洁净室施工及验收规范》

Code for construction and acceptance of cleanroom

GB/T 16293-2010 《医药工业洁净室(区)浮游菌的测试方法》

Test method for airborne microbe in clean room (zone) of the pharmaceutical industry

GB/T 16294-2010 《医药工业洁净室(区)沉降菌的测试方法》

Test method for settling microbe in clean room (zone) of the pharmaceutical industry

本次检测结果判定所依据的技术规范:

Judgment basis used for the results in the detection

GB 50073-2013 《洁净厂房设计规范》

Code for design of clean room

YY/T 0033-2000 《无菌医疗器械生产管理规范》

Good manufacture practice for sterile medical devices

声明:

Statement

1.报告未盖本公司“报告专用章”和审核、批准人签字,一律无效。The report is invalid without “Special Seal for the Report” and without the signature of the inspector and the approver.

2.未经本公司批准授权,不得部分采用本报告。

This certificate may not be used partly without the approval and authorization of the company.

3.复制的报告未重新加盖“报告专用章”无效。

The complete copy is invalid without the stamp of “Special Seal for the Report”.

4.本报告的检测结果仅与受检测样品有关,并仅对检测时的状况负责。

The test results of this report are only valid for the tested sample and the situation during the test.

5.在中华人民共和国境内,报告若未加盖CMA章,表示本检测报告仅用于客户科研、教学、内部质量控制、产品研发等目的,仅供内部参考。

In the territory of the People's Republic of China, the detection report without CMA logo expresses the detection report shall only used for client scientific research, teaching, internal quality control, product research and development, etc., and just for client internal reference.

6.如对报告有疑问,请在收到报告后15个工作日内提出。

Any queries on the report shall be presented to us within 15 working days after receipt of the report.



本次检测所使用的主要标准器具:

Main measurement instruments used in the detection

名称 Name	编号 No.	测量范围 Measuring Range	不确定度或准确度等级或最大允许误差 Uncertainty or Accuracy Class or MPE.	溯源机构 Traceability institution	证书编号/有效期至 Certificate No. / Due Date
尘埃粒子计数器 Particle counter	510305	采样流量: 28.3L/min	粒子浓度示值允差: $\pm 30\%FS$	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	525013987-001 2026-05-20
尘埃粒子计数器 Particle counter	510288	28.3L/min	MPE: $\pm 30\%FS$	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	525013984-003 2026-05-20
浮游菌采样器 Plankton sampler	205579	100L/min	MPE: $\pm 5\%$	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	524019290-001 2025-12-14
浮游菌采样器 Plankton sampler	205577	100L/min	MPE: $\pm 5\%$	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	525013988 2026-05-20
风量仪 Air flow hood	Wit5620230315	(100~3500)m ³ /h	$\pm 5\%FS$	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	524018759 2025-11-24
温湿度记录仪 Temperature and humidity recorder	83634112/83933599/83933614/84131815/84125237	温度: (-20~50) °C, 湿度: (10~90) %RH	温度: $\pm 0.5^{\circ}C$, 湿度: $\pm 3.0\%$ Temperature: $\pm 0.5^{\circ}C$, Humidity: $\pm 3.0\%$	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	525024962-036~040 2026-07-05
声级计 Sound level meter	220802757	35dB-130dB	$U = (0.4 \sim 0.6) dB, k=2$	苏州国方计量集团有限公司 Suzhou Guofang Metrology Group Co., Ltd.	AD11909916 2025-12-26
照度计 Illuminometer	100358666	(50~20000) lx	$U_{rel}=3.2\%, k=2$	苏州国方计量集团有限公司 Suzhou Guofang Metrology Group Co., Ltd.	AG11901774 2025-12-26



本次检测所使用的主要标准器具:

Main measurement instruments used in the detection

名称 Name	编号 No.	测量范围 Measuring Range	不确定度或准确度等级或最大允许误差 Uncertainty or Accuracy Class or MPE.	溯源机构 Traceability institution	证书编号/有效期至 Certificate No. / Due Date
生化培养箱 Biochemical incubator	220843568	(0~60)°C	$U=0.4^{\circ}\text{C}$, $k=2$	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	525027403 2026-08-05
数字压力计 Digital pressure gauge	SUBMCDE3072	(0~100) hPa	0.5级	微谱检测(苏州)有限公司 WEIPU Testing Technology (Suzhou) Co., Ltd	524019292 2025-12-19



检测结果

RESULTS OF DETECTION

受检区域名称: Tested area:		组装车间1 Assembly workshop 1		洁净等级: Cleanliness level:		100000		检测状态: Testing condition:		静态 at rest		
面积: Built-up area:		740.00 m ²		层高: Floor height:		3.00 m		体积: Volume:		2220.00 m ³		
检测项目 Test items		检测方法 Test basis		技术要求 Technical requirement				检测结果 Test result		结论 Conclusion		
风量 Air volume (m ³ /h)		GB 50591-2010		满足换气次数≥15次/h的风量要求 Meet the air volume requirement of number of air changes ≥ 15 times/h 备注: 换气次数=总风量/房间体积 Note: Number of air changes=Total air volume/Room volume				40933.0		合格 Pass		
								换气次数 Number of air changes = 18 次/h times/h				
温度 Temperature (℃)		GB 50591-2010		18~28				21.4		合格 Pass		
湿度 Humidity (%RH)		GB 50591-2010		45~65				54.8		合格 Pass		
静压差 Static pressure difference (Pa)		GB 50591-2010		组装车间1 相对于 缓冲间 Assembly workshop 1 Relative to buffer room ≥5				11		合格 Pass		
洁净度 Cleanliness (个/m ³)		GB/T 16292-2010		≥0.5 μm: ≤3500000				Amax		4806		合格 Pass
				≥5.0 μm: ≤20000				Amax		1497		
噪声 Sound level (dB (A))		GB 50591-2010		≤60				56.9		合格 Pass		
照度 Illuminance (lx)		GB 50591-2010		≥200				304		合格 Pass		
浮游菌 Airborne microbe (CFU/m ³)		GB/T 16293-2010		≤500				80		合格 Pass		
沉降菌 Settling microbe (CFU/皿, 2.5h)		GB/T 16294-2010		≤10				5		合格 Pass		



检测结果

RESULTS OF DETECTION

受检区域名称: Tested area:		组装车间2 Assembly workshop 2		洁净等级: Cleanliness level:		100000		检测状态: Testing condition:		静态 at rest		
面积: Built-up area:		940.00 m ²		层高: Floor height:		3.00 m		体积: Volume:		2820.00 m ³		
检测项目 Test items		检测方法 Test basis		技术要求 Technical requirement				检测结果 Test result		结论 Conclusion		
风量 Air volume (m ³ /h)		GB 50591-2010		满足换气次数≥15次/h的风量要求 Meet the air volume requirement of number of air changes ≥ 15 times/h 备注: 换气次数=总风量/房间体积 Note: Number of air changes=Total air volume/Room volume				44557.0		合格 Pass		
								换气次数 Number of air changes = 15 次/h times/h				
温度 Temperature (℃)		GB 50591-2010		18~28				21.8		合格 Pass		
湿度 Humidity (%RH)		GB 50591-2010		45~65				53.8		合格 Pass		
静压差 Static pressure difference (Pa)		GB 50591-2010		组装车间2 相对于 一般区 Assembly workshop 2 Relative to general area ≥5				14		合格 Pass		
洁净度 Cleanliness (个/m ³)		GB/T 16292-2010		≥0.5 μm: ≤3500000				Amax		16643		合格 Pass
				≥5.0 μm: ≤20000				Amax		1920		
噪声 Sound level (dB (A))		GB 50591-2010		≤60				56.3		合格 Pass		
照度 Illuminance (lx)		GB 50591-2010		≥200				311		合格 Pass		
浮游菌 Airborne microbe (CFU/m ³)		GB/T 16293-2010		≤500				60		合格 Pass		
沉降菌 Settling microbe (CFU/皿, 2.5h)		GB/T 16294-2010		≤10				5		合格 Pass		



检测结果

RESULTS OF DETECTION

受检区域名称: Tested area:	注塑车间1 Injection workshop 1	洁净等级: Cleanliness level:	100000	检测状态: Testing condition:	静态 at rest	
面积: Built-up area:	688.00 m ²	层高: Floor height:	4.50 m	体积: Volume:	3096.00 m ³	
检测项目 Test items	检测方法 Test basis	技术要求 Technical requirement		检测结果 Test result		结论 Conclusion
风量 Air volume (m ³ /h)	GB 50591-2010	满足换气次数≥15次/h的风量要求 Meet the air volume requirement of number of air changes ≥ 15 times/h 备注: 换气次数=总风量/房间体积 Note: Number of air changes=Total air volume/Room volume		50954.0		合格 Pass
				换气次数 Number of air changes = 16 次/h times/h		
温度 Temperature (℃)	GB 50591-2010	18~28		21.9		合格 Pass
湿度 Humidity (%RH)	GB 50591-2010	45~65		54.3		合格 Pass
静压差 Static pressure difference (Pa)	GB 50591-2010	注塑车间1 Injection workshop 1	相对于一般区 Relative to general area	≥5 15		合格 Pass
洁净度 Cleanliness (个/m ³)	GB/T 16292-2010	≥0.5 μm: ≤3500000		Amax	19552	合格 Pass
		≥5.0 μm: ≤20000		Amax	802	
噪声 Sound level (dB (A))	GB 50591-2010	≤60		56.3		合格 Pass
照度 Illuminance (lx)	GB 50591-2010	≥200		286		合格 Pass
浮游菌 Airborne microbe (CFU/m ³)	GB/T 16293-2010	≤500		70		合格 Pass
沉降菌 Settling microbe (CFU/皿, 2.5h)	GB/T 16294-2010	≤10		6		合格 Pass



检测结果

RESULTS OF DETECTION

受检区域名称: Tested area:	注塑车间2 Injection workshop 2	洁净等级: Cleanliness level:	100000	检测状态: Testing condition:	静态 at rest	
面积: Built-up area:	694.00 m ²	层高: Floor height:	4.50 m	体积: Volume:	3123.00 m ³	
检测项目 Test items	检测方法 Test basis	技术要求 Technical requirement		检测结果 Test result		结论 Conclusion
风量 Air volume (m ³ /h)	GB 50591-2010	满足换气次数≥15次/h的风量要求 Meet the air volume requirement of number of air changes ≥ 15 times/h 备注: 换气次数=总风量/房间体积 Note: Number of air changes=Total air volume/Room volume		49667.0		合格 Pass
				换气次数 Number of air changes = 15 次/h times/h		
温度 Temperature (℃)	GB 50591-2010	18~28		21.5		合格 Pass
湿度 Humidity (%RH)	GB 50591-2010	45~65		56.2		合格 Pass
静压差 Static pressure difference (Pa)	GB 50591-2010	注塑车间2 相对于 一般区 Injection workshop 2 Relative to general area ≥5		14		合格 Pass
洁净度 Cleanliness (个/m ³)	GB/T 16292-2010	≥0.5 μm: ≤3500000		Amax	9600	合格 Pass
		≥5.0 μm: ≤20000		Amax	2262	
噪声 Sound level (dB (A))	GB 50591-2010	≤60		56.1		合格 Pass
照度 Illuminance (lx)	GB 50591-2010	≥200		252		合格 Pass
浮游菌 Airborne microbe (CFU/m ³)	GB/T 16293-2010	≤500		50		合格 Pass
沉降菌 Settling microbe (CFU/皿, 2.5h)	GB/T 16294-2010	≤10		4		合格 Pass

---报告内容结束---
---End of the Report---