# 层流罩 Laminar flow unit

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### 苏州华泰空气过滤器有限公司 SUZHOU HUATAI AIR TECH FILTER CO., LTD

## **About Us**

### 企业简介

苏州华泰空气过滤器有限公司是由江苏苏净集团、苏州相城区吴净净化设备有限公司二方投资组建而成。专 业生产空气过滤器、空气过滤纸、洁净单元和化学空气过滤器。

华泰公司从日本引进数条目前世界上最先进的无隔板过滤器生产线及专有技术。为保证产品品质,所有高效 过滤器在10万级洁净环境内生产、检测、包装。公司自行生产各类玻璃纤维空气过滤纸,是国内唯一一家既生产 过滤器又生产过滤纸的公司。

华泰公司注重产品开发,成立了空气过滤器及洁净单元的研究中心,建立了化学实验室。拥有MPPS全效率 检测仪、DOP检测仪、计数扫描仪、化学过滤器测试线、美国进口0.1um大流量激光尘埃粒子计数器和氨、硫化 氢分析仪及多种气体校验仪等试验检验设备,实施产学研共建开发模式,相继开发生产了0.1微米UPLA过滤器、 化学过滤器、同时处理分子态污染物的FFU及多种洁净单元。

华泰公司具有良好的品质、服务体系,于1998年12月顺利通过ISO9001质量管理体系认证,于2001年12月 通过ISO14001环境管理体系的认证。公司建立了较为完善的服务体系,愿为广大用户提供周到、完善、细致的 专业服务。

### 华泰人始终以"满足广大用户要求","创造适用于各种环境的洁净空气"为努力目标。

Suzhou Huatai Air Tech Co., Ltd., a joint venture of Jiangsu Sujing Purification Group and Xiangcheng district Wujing Purification Equipment Co., Ltd., is a special company in the production of air filters, filter media, clean unit and chemical filters.

Our company has imported both up-to-date production line and advanced technology from Japan for manufacturing min-pleat air filters. Further more ,the company has the ability of the producing, testing and packaging air filters in clean rooms of class 100,000, so that it enable the quality of air filters to be a high level.We also manufacture filter media of various glass fiber and become the sole company in China with the production ability in air filter as well as in filter media.

Our company focuses on product development. It has set up a research center of air filter and clean unit and also established a Chemical laboratory. We have MPPS full efficiency detector . DOP detector, count scanner. chemical filter test line. US imported equipment including 0.1um High-volume laser particle counter and Ammonia, hydrogen sulfide gas analyzer and a variety of gas Calibrator and so on . We carry out the mode which manufacture, teaching and researching build at the same time. We has developed and produced a 0.1-micron ULPA filters, chemical filters, FFU and a variety of clean unit which can dealing with the AMC at the same time.

The company has a well organized quality management system. In December 1998, the company was successfully awarded the Certification of ISO9001 quality management system. In December 2001, the company was successfully awarded the Certification of ISO14001 environmental management system. The company has established a relatively perfect service system willing to provide customers with thoughtful, comprehensive, detailed and professional service.

The company always takes 'Meeting the requirement of client and Creating clean air for various environments' as our targets and strives for it.



### Laminar flow unit 层流罩(RABS)

### 工作原理:

层流罩是能将操作员与产品屏蔽隔离的设备之一,其主要 用途是避免产品污染。内部增压舱里安装的风机从洁净室吸取 的空气,然后通过HEPA过滤后垂直穿过操作区域,为关键区 域提供A级的单向流洁净空气。它主要由箱体、风机、高效空 气过滤器、阻尼层、灯具及控制系统等组成。

Operation principle:

Laminar flow unit is one of the equipment to isolate workers from products; the main purpose of it is to avoid product contamination. Inside the internal pressure cabin installed is a blower that absorbs air from clean room. The air is then filtered by HEPA and goes through the operation area vertically, providing critical areas with class A unidirectional clean air. The unit consists of box, blower, high-efficient filter, damping layer, lighting apparatus, and control system etc.



### 特点:

- 1、箱体及各部件均采用SUS304制作,根据现场层高设计负压式或正压式结构,满足药厂生产环境需要;
- 2、模块式结构,可根据现场生产要求及设备布局设计安装;
- 3、设置高效过滤器PAO扫描检漏接口,及压损监测,可有效评价过滤器安装确认及使用情况
- 4、层流罩进风方式为侧进或顶进,各项指标满足2010版GMP及欧盟GMP要求;
- 5、可根据客户要求要求实现风速反馈、变频调速、各项指标报警和触摸屏操作等功能。

#### Features:

- 1, The box and components are made of SUS304, fulfilling the production environment needs of pharmaceutical plant by designing negative or positive pressure structure according to the site floor height.
- Module structure with which the installation can be designed according to the site production needs and equipment layout. 3. Provided with high-efficiency filter PAO scan leakage detecting interface as well as pressure loss monitoring that can
- effectively evaluate the filter installation and use.
- The laminar flow unit takes in air from side or top, with each indicator in compliance with 2010 GMP or EU GMP. Wind speed feedback, inverter speed control, indicator alarm and touch screen operation etc can be realized as required by the customer.

### 性能参数:

### Performance parameters:

项目 Item 指标 Indicator	洁净等级 Cleanliness class	平均风速 Average wind speed	噪 声 Noise	照 度 Luminance
	A 级	0.45m/s±20%	≤65dB	≥300LAX

#### 层流罩尺寸可定制生产

Size of the laminar flow unit can be customized.

# Weighing unit

### 称量置

称量罩是一种用于制药、微生物研究和科学实验等 场所专用的局部洁净设备,它提供一种垂直单向气流,部 分洁净空气在工作区循环,部分排出至附近区域,使工 作区产生负压,防止交叉污染,用于保证工作区的高洁。 净度环境。在设备中进行粉尘、试剂称量、分装,可以 控制粉尘、试剂外溢、上扬,防止粉尘、试剂对人体的 吸入危害,还避免粉尘、试剂的交叉污染,保护外界环 境及室内人员的安全。

### 特点:

- 1、设置三级过滤,有效处长末端高效过滤器寿命;
- 2、通过调整外排风量,调节操作区内负压差(操作 面须设置物理围护);
- 3、满足各种材料的称量、分装等工艺,保护背景环 墙及操作人员不受污染:
- 4、可对各项性能指标进行监测,并提供报警信息, 确保系统受控:
- 5、称量罩内设置各种性能检测接口及设备使用电源 接口,方便操作。

Weighing unit is special local clean equipment for pharmaceutical, microorganism research, and scientific experiment places etc. It provides vertical unidirectional air flow, with part of the clean air circulating in work area and some of the clean air discharged to the nearby areas, so that the work area can produce negative pressure to prevent cross contamination, ensuring a highly clean environment in the work area; weighing and dividing dust and reagents in the equipment can control generation of dust, reagent overflowing, flying, thus to prevent hazards of dust and reagent to human bodies by inhalation as well as to prevent cross contamination of dust and reagent, protecting safety of the external environment and personnel indoor.

#### Features:

- 1. Provided with three-stage filtration that effectively maximize the service life of the high-efficient filter at the ond
- Adjusting the discharge air volume can adjust the negative pressure value in the operation area (physical protection must be provided to the operation face). Meeting the requirements of the processes of various
- materials for weighing and dividing; protecting the background environment and operation personnel from contamination The performance indicators can be monitored and
- provided with alarm information to ensure the system is under control. Inside the weighing unit provided are various
- performance testing interfaces and power connection ports to facilitate use of the unit



### 参考标准:

- 1、符合中国GMP2010修订版(第五十二条、五十 三条)、美国FDA cGMP、欧盟cGMP的要求
- 2、《药品生产质量管理规范》2010版
- 3、《药品 GMP 指南》 2010 版
- 4、电气元器件通过国家强制 CCC 认证 5、Gb50457-2008《医药工业洁净厂房设计规范》
- 6、GB 50591-2010《洁净室施工及验收规范》

### Reference standards:

- 1. In compliance with China GMP2010 revised version (clause 52 and 53), USA FDA cGMP, and EU cGMP 2, Good Manufacturing Practice for Drugs, version
- 2010 3. GMP Guide for Drugs, version 2010
- 4. Electrical components are CCC certified
- 5, GB50457-2008 Code for design of pharmaceutical industry clean room
- 6. GB 50591-2010 Clean Room Construction and Acceptance Code

### 面对日益严格的GMP要求,制药工业越来越重 视对生产环境的粒子和细菌的控制及防护,因此对清 洗及无菌的要求越来越严格。同时要求对于某些有毒 产品,对操作人员进行更高水平的保护,隔离技术在 制药行业中广泛应用。

方式:根据客户工艺需要,外形尺寸及功能(温

湿度,相对压差)均可定制; 功能:垂直单向流或涡流,保护产品和人员,洁

净等级A级,可循环回风(或袋讲袋出); 场所:可应用于灌装线、烘箱、冻干或湿热灭茵

器、三合一等出料,称量、配液和无菌测试等场所。 特点:可进行多种验证测试, VHP灭茵和与各 种容器及系统接口。





**ISOLATOR** 

隔离器

Facing the GMP requirements that become more and more rigorous, people in pharmaceutical industry put more and more attention on control and protection of particles and germs in production environment, therefore, the requirements for cleaning and asepsis gets more and more strict; at the same time, for some poisonous products, the operators needs protection of higher level, thus isolation technique is extensively applied in pharmaceutical industry.

Form: can be tailored according to the customer's process requirements, external dimensions and functions (temperature and humidity, relative differential pressure).

Function: vertical unidirectional flow or eddy flow to protect products and personnel; class A cleanliness, air can circulate (or bag in/out).

Place: the unit can be used with filling line, oven freezing dry or steam sterilizer, 3-in-1 discharge, weighing, liquid preparation and aseptic testing places.

Features: a number of verification and tests can be performed; VHP sterilization is interfaced with various containers and systems.

◎ 隔离器内部细节

O Details inside the











# **ISOLATOR**

### 隔离器



· 温湿度在线监测 System online monitoring: · Monitor online acc. to the cleanliness at several points in class A area Online monitoring of microorganism(airborne bacteria)
 Online monitoring of temperature/humidity

微生物(浮游菌)在线监测院

• 根据A级区面积多点洁净度在线监测置设计,并提出DQ方案;

· 按用户要求起草3Q(IQ、OQ、PQ)文件,进行确认验收

Design acc. to process equipment layout and propose for DQ

• Work out 3Q (IQ, OQ, PQ) document as required by the customer for validation and acceptance.

系统在线监测

技术支持及服务:

Technical support:

· Can provide FAT, SAT

根据工艺设备布

• 可提供FAT、SAT

服无菌出料时用半身衣 Half-body clothes for sterilized discharge



无菌手套在线测试 Online test of aseptic gloves



验证接口 Verification interface

- 相对压差在线监测
- A级风速在线监测
- 监测数据保存及打印功能
- · Online monitoring of relative differential pressure Class A wind speed online monitoring
- · Saving and printing function of monitored data





CIP online cleaning system



CIP在线清洗系统



[01]Docking 传递舱与实验舱对接 Docking between relay cabin and experiment cabin

RTP system principle

RTP系统图示



[02]Closed 顺时针旋转手柄30度,卡紧双门, 将污染空气屏蔽在夹层内。 Rotate the handle clockwise for 30 degrees; securely tighten the two doors to isolate contaminating air in the interlayer



◎ 图中白色部分为洁净区,灰色部分为非洁净区 In the diagram, white area means clean area; grey section means non-clean area

[03]Free transmission 打开传递门,实现两个无菌舱之 间的自由传递。 Open the relay door to realize automatic relay between two aseptic cabins.

### 苏州华泰空气过滤器有限公司 SUZHOU HUATAI AIR TECH FILTER CO.,LTD Ð

# PASS BOX

# 传递窗

### 产品介绍

传递窗是与洁净厂房配合使用的空气净化设备。适用于洁净室与 洁净室之间或洁净室与非洁净室之间的中、小型货物的传递。使用该 传递窗后,可减少洁净室的关门次,把洁净区的污染降到最低程度。

#### Product Introduction

Pass box is a kind of equipment for matching with clean plant in order to purify the air; it's applicable to pass of medium and small size goods between clean rooms or clean room and non-clean room. With this pass box, the times of door opening/closing of the clean room can be minimized, thus to maximally reduce the contamination degree of the clean area.

### 产品的演变

Evolution of the Product





苏州吴江区汾湖开发区金家坝金盛路 1048号 电话:0512-63205920 63210863 传直:0512-63203884

### 传统样式的传递窗内部四侧的 过渡是直角的,清洁时比较困难。

Traditional pass box has four inner sides transitioned with right angles, which makes cleaning difficult.

#### 传递窗内部四侧的过渡由直角 更改为圆弧角的,清洁时比较方 便

The transition of the four inner sides of the pass box is changed from right angle to arc angle to facilitate cleaning.

门的顶部制作一罩板,防止门 顶部因无遮拦而灰尘堆积。

A cover plate is provided at the top of the door to prevent accumulation of dust for without protection.



### 原圆弧过渡玻璃视窗,在频繁使用之后或者经过人员的经常拍打,玻璃会 跌落,客户很难去更换和安装,故定开型材来固定玻璃,方便安装与更换。

The former arc-transitioned sight glass will fall off after frequent use or frequent patting by the operator, making it's difficult for the user to replace and install. Therefore, fixed materials are used to secure the glass to facility installation and replacement.



#### 此款除了玻璃固定方式改进意外。铰链采用了加厚型合金材质,保证门体 在长期频繁使用的情况下不出现异常状况。密封条也修改为食品级硅胶材质, 用型材固定。密封条和型材都是定开的模具。

In addition to improvement with fixed glass, the hinge of this model adopts thickened alloy material to prevent anomaly for long-term and frequent use of the door; the seal stripe adopts food-grade silicone material that is fixed with section material properly. Both the seal stripe and the section material are mad with tailored mold.

#### 此款门与箱体平齐,铰链和密封条都区别于常规产品,玻璃视窗为中空玻 璃但是由于门体较重,经常使用之后有调角的风险,一般不推荐使用。且碎了 不易配,一般不推荐使用。现改为单层方形视窗,均可解决。

The door of this model is leveled with the box: both the hinge and the seal stripe are different from general products; the sight glass adopts hollow version, however, since the door is heavy, it may have corner changed and it's not easy to replace the broken glass, thus it's not recommended to use it. Now the sight is changed into single-layer square type to solve the problem.

















ISO 9001 | ISO 14001 Certified by BTCC Certified by BTCC

# **Product Classification**

### 产品的分类

### 洁净传递窗 Clean Pass Box

洁净式传递窗是安装在洁净室、生物实验室墙面或者其他洁净设备上 的箱体,主要用于洁净区与洁净区之间,洁净区与非洁净区之间物料的传 递,以减少洁净室的开门次数把对洁净室的污染降到最低程度。

在物料通过传递窗时,通过HEPA过滤器的洁净气流会快速有效的清除 尘埃粒子,清除后气流的再由初、高效过滤器过滤后重新循环到洁净区域 内,因此洁净式传递窗较普通传递窗性能更佳。洁净式传递窗的基本洁净 时间设定为30秒。也可以根据客户要求进行定制。

Clean pass box is to install on the wall of clean room, biological lab or on other clean equipment, mainly for passing materials between clean areas or between clean area and non-clean area, so as to minimize the times of door opening/closing of the clean room and maximally reduce the contamination of the clean room.

When the materials goes through the pass box, the clean air flow through HEPA filter can quickly and effectively remove the dust particles; then the air flow is filtered by the primary and high level filter and returns to clean area; thus clean pass box has better performance as compared with general pass boxes. The basic clean time of clean pass box is set as 30 seconds; it can also be failored according to the requirement of the customer.

### 特点

◎ 箱体选用优质 304不锈钢,光洁平整易清洁

◎ 永久润滑直动式离心风机

无隔板 HEPA高效过滤器,对0.3微米的尘埃粒子的过滤效率为>99.99%
 可使用不锈钢喷嘴提供高速气流,更有效的清除尘埃粒子(常规为均流板

◎ 低噪音,工作状态噪音低于60分贝

◎ 电子互锁系统防止内外气流贯穿

◎ 装有专门的卫生级硅胶密封条,以确保气密性

◎ 结构强化设计确保安全性

◎ 安装简易,洁净室兼容性佳

安装有压差表,时刻监控过滤器的使用状况
 可加装 DOP测试口,检测高效过滤器的完整性

### Features

- O The box is made of SS 304 that is bright, clean and easy to clean;
- Permanently lubricated direct-acting centrifugal fan;
- O High-efficiency filter (HEPA) without partition has a filtering efficiency over 99.99% for 0.3-micron dust particles.
- Stainless steel nozzle is adopted to provide high-velocity air flow to effectively remove dust particles (flow equalizing plate is adopted for general version).
- Low noise: noise in work mode is below 60 dB(A).
- © Electronic interlock system preventing penetration of inside and outside airflow.
- O Special-purpose hygienic silicone seal stripe is provided to ensure air tightness.
- O Enhanced structure design to ensure safety.
- Easy installation for good compatibility of the clean room.
- O Differential pressure gauge is provided for always monitoring use of the filter.
- O DOP test port can be provided to detect the completeness of the high-efficiency filter.





#### 基本规格 Pasis Spasi



### 可选性能/配件

ULPA高效过滤器、钢化玻璃窗门、传送带装置 (滚轮)、活性碳过滤器、紫外线杀菌灯、臭氧发生 器、压差表、DOP测试口、杀菌灯定时器、电子(电磁 力)互锁、机械互锁、日光灯等。

### Optional functions/parts

High-efficiency ULPA filter, tempered glass door, conveyor belt (roller type), active carbon filter, UV germicidal lamp, cone generator, differential pressure gauge, DOP test port, timer for germicidal lamp, electronic (electromagnetic) interlock, mechanical interlock, fluorescent lamp etc.

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### 说明

常规的门轴由于长时间的使用会导致图一的状况, 直接导致门体下垂,互锁失灵,严重时会导致门体报 废。经过长时间的研究和实践,我公司通过在门轴上加 装机构改良已经大大的提高的门体的使用寿命,时间证 明现有门轴传递窗的使用寿命已经是改良前传递窗使用 寿命的3-5倍。



### Introduction

General door shaft is likely to be as shown in the following figure for long-time use, which directly cause the door to droop and the interlock out of work; in serious circumstance, the door will be scrapped. We, through longme research and practice, provide interlocking mechanism on the door shaft that greatly improve the service life of the door; as proved for times, the pass box with the present door shaft has a service life 3-5 times of the version before improvement.



### **Other Types of Clean Pass** 其他类型洁净传递





带新风传递窗 Fresh air pass box



镜面传递窗 Mirror face pass box



仿进口传递窗 Imitated imported pass box



Mirror face pass box



仿进口传递窗 Imitated imported pass box

# **General Pass Box**

### 普通传递窗

传递窗是安装在洁净室、生物实验室墙面或者 其他洁净设备上的箱体,是传递小体积货品进出洁 净区域通道,用来减少开门次数以降低尘埃对洁净 室的污染。当设备和材料通过传递窗时,所装备的 电子互锁系统将确保两扇窗门不会同时打开。

Clean pass box is to install on the wall of clean room, biological lab or on other clean equipment, mainly for passing small-volume goods in/out of clean area, so as to reduce the times of door opening/closing of clean area, so as to reduce contamination of the clean area by dust. When equipment and materials go through pass box, the electronic interlocking system will ensure that the two window blades will not be opened at the same time.



罩板式电子 Electronic cover plate type

### 特点

◎ 外壳选用优质304不锈钢材料也可选用钢板材料, ◎ The outer housing adopt quality SS 304; steel plate

- 附环氧树脂涂层
- ◎ 内胆为304不锈钢,四侧圆弧过渡,光洁平整易清洁
- ◎ 装有专门的食品级硅胶密封条,以确保气密性
- ◎ 机械或电子互锁系统和结构强化设计确保安全性
- ◎ 安装简易,洁净室兼容性佳
- ◎ 可根据客户要求定制

### 基本规格

**Basic Specifications** 

		coated with epoxy resin can also selected.
	0	The liner is SS304 with four sides transitioned with arc
ŧ.		design that is bright, neat and easy to clean.
	-	

General mechanical type

Features

- O Special-purpose food-grade silicone seal stripe to
- tem and
- an room.

	opeciai-parpose rood-grade sincone sear a				
	ensure air tightness.				
0	Mechanical or electronic interlocking syst				
	enhanced structure design to ensure safety.				
0	Easy installation, good compatibility of the clea				
0	Can be customized as required by the custome				

型号 Model	CD-500	CD-600	
外尺寸(宽x深x高,mm) Outer dimensions (WxDxH, mm)	655 x 570 x 590 mm	755 x 670 x 690	
内尺寸(宽x深x高,mm) 毛重 (kg) Inner dimensions (WxDxH, mm) Gross weight (kg)	500 x 500 x 500 mm 110 kg	600 x 600 x 600 mm 140 kg	
净重(kg) Net weight (kg)	80 kg	110 kg	
装箱尺寸(宽x深x高,mm)	810 x 810 x 740 mm	910 x 910 x 840 mm	





### 可选性能配件

**Optional Parts** 

 1. 机械互锁
 Mechanical interlock

 2. 电子互锁
 Electronic interlock

 3. 电磁力互锁
 Electromagnetic interlock

 4. 杀脑灯
 Germicidal lamp

 5. 日光灯
 Fluorescent lamp

## Other Types of General Pass Boxes 其他类型普通传递窗





# Other Non-standard Pass Box



定时器开关传递窗 Pass box with timer switch



超大型双开门 Ultra-large double door



其他非标类型传递窗

折角传递窗 Fold-corner pass box



四面杀菌灯传递窗(杀菌时间可调) Pass box with germicidal lamp on four sides (sterilization time adjustable)



流水线用传递窗 Pass box for production line



内嵌式普通传递叠加型 Embedded general pass box, overlap type

ISO 9001 | ISO 14001 Certified by BTCC | Certified by BTCC

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