



## Recommended Clean Air Equipment for USP <797> and USP <800> Facilities

Configured for ISO Class 5 workspace as required by USP <797> for pharmaceutical lab environments



# Brief summary of requirements for equipment

USP <797> and USP <800> are chapters within the USP containing new requirements for equipment and facilities used in the preparation of compounded sterile hazardous drugs (HDs) and non-hazardous drugs (non-HDs). These include very specific requirements for the Primary Engineering Controls (PECs) and Containment Primary Engineering Controls (C-PECs) needed as work stations within the cleanroom facilities. The engineering controls described within these chapters are differentiated by whether they provide clean air for aseptic processing, hazardous drugs containment for personal protection, or both.

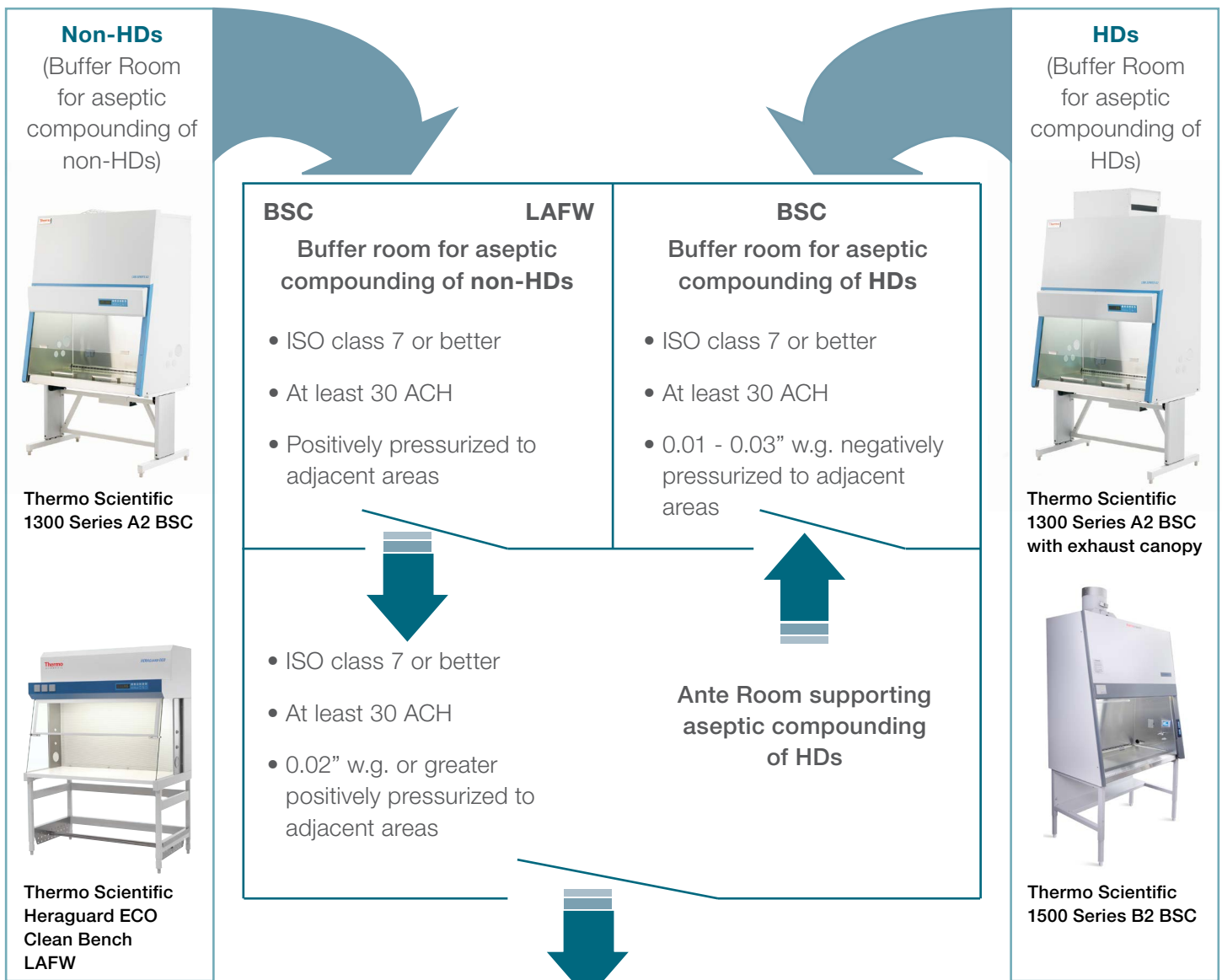
## PEC and C-PEC differentiated by clean air and containment

	Provides clean air for aseptic processing	Aseptic processing is not required
Provides containment of hazardous drugs	C-PEC as described by USP <800>. Examples are Class II, Types A2 (with canopy connection), B1 or B2; Class III BSC or CACI (Compounding Aseptic Containment Isolator)	C-PEC as described by USP <800>. Examples are CVE (Containment Ventilated Enclosure), Class I or II BSC, CACI (Compounding Aseptic Containment Isolator)
Containment is not required	PEC as described by USP <797>. Examples are LAFW (Laminar Airflow Workbench), integrated vertical laminar flow zones (IVLFZs), and Class II BSCs	

NOTE: Other chapters in the USP may also require specific facilities and equipment. For example, the proposed USP[795] requires a CVE for containment of potential API airborne contamination

# Placement of equipment in cleanrooms

The Primary Engineering Controls are optimally placed within cleanrooms that serve as Secondary Engineering Controls. Depending on the use and function, these cleanrooms have differing requirements for pressurization and air cleanliness. Here is a graphical representation of some of the requirements for the primary and secondary engineering controls presented in USP <797> and USP <800>. Each cleanroom is described as to air cleanliness, ventilation in air changes per hour (ACH) and pressurization relative to adjacent areas.



# Clean air equipment

The Thermo Scientific™ 1300 Series A2 BSC is an NSF listed Class II, Type A2 biosafety cabinet with dual wall construction for greater containment, SmartFlow compensation to better maintain personal and product protection as filters load, DAVE (Digital Airflow Verification) to alert users should inflow or downflow vary from set points by 20% or more, and long life energy efficient DC motors. The models listed below are equipped with stainless steel interiors and 10" front openings for easier access.

Meets the requirements of a PEC, USP <797> and a C-PEC, USP <800>. It provides an air cleanliness of ISO Class 5 and has unidirectional airflow that sweeps particles away from the compounding area. For use in preparing hazardous drugs under USP <800> it must be equipped with the available exhaust canopy and external exhaust alarm.



# Thermo Scientific 1500 Series B2 BSC

**The Thermo Scientific 1500 Series B2 BSC is an NSF listed Class II, Type B2 biosafety cabinet with stainless steel interior, 8" opening, flow compensation to better maintain downflow as filters load, and an energy efficient DC downflow motor.**

Meets requirements of a C-PEC, USP <800> when preparing hazardous drugs with volatile components. It provides an air cleanliness of ISO Class 5 and has unidirectional airflow that sweeps particles away from the compounding area. This type of cabinet has greater requirements for external exhaust when compared to Class II, Type A2 BSCs equipped with thimble connections.



## **Selecting Type A2 or Type B2**

Class II, Type B2 BSCs are more demanding with larger exhaust volume requirements and higher negative static pressure. They need to draw more exhaust air against greater resistance. These units are recommended to be connected to dedicated exhaust systems where one cabinet is connected to one duct which is connected to one exhaust fan on the roof. In contrast, thimble connected Class II, Type A2 BSCs require less exhaust and can be served by “ganged” exhaust systems that are connected to other equipment and systems.

One of the points of confusion in selecting a Class II BSC for compliance to USP <797> and USP <800> is whether a Type A2 or Type B2 is appropriate. USP <800>, Section 5.3.2 states *“For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components.”*

### BSC Specifications and ordering information

Type	Description	Cat. No.
1300A2	3 ft Class II, Type A2 BSC with stainless steel interior, stand, UV and armrests	1323
1300A2	4 ft Class II, Type A2 BSC with stainless steel interior, stand, UV and armrests	1375
1300A2	5 ft Class II, Type A2 BSC with stainless steel interior, stand, UV and armrests	1371
1300A2	6 ft Class II, Type A2 BSC with stainless steel interior, stand, UV and armrests	1377
Exhaust accessory allowing 1300A2 to handle hazardous drugs	Thimble connection for 3, 4, and 5 ft 1300A2 units	1911316
Exhaust accessory allowing 1300A2 to handle hazardous drugs	Thimble connection A2 for 6 ft 1300A2 units	1911317
Exhaust alarm allowing 1300A2 to handle hazardous drugs	Alnor exhaust alarm for 1300 Series A2 biological safety cabinets	1910185
IV Bar	IV bag holder kit with 6 hooks (for 3 foot A2 cabinet only)	1911413
IV Bar	IV bag holder kit with 12 hooks (for 4 foot, 5 foot, and 6 foot A2 cabinets)	1911312
1500B2	4 ft Class II, Type B2 BSC	1510
1500B2	6 ft Class II, Type B2 BSC	1560
Stand for B2	Adjustable floor stand for 4 ft 1500 B2. Provides variable work height of 30" to 36" adjustable by one inch increments	3730402
Stand for B2	Adjustable floor stand for 6 ft 1500 B2. Provides variable work height of 30" to 36" adjustable by one inch increments	3730602
IV Bar	IV Bag Holder Kit for 4 foot B2 cabinet	3858611
IV Bar	IV Bag Holder Kit for 6 foot B2 cabinet	3858613
Heraguard ECO	3 ft Horizontal Flow Clean Bench	51029691
Heraguard ECO	4 ft Horizontal Flow Clean Bench	51029692
Heraguard ECO	5 ft Horizontal Flow Clean Bench	51029693
Heraguard ECO	6 ft Horizontal Flow Clean Bench	51029694
Stand for Clean Bench	Adjustable floor stand for 3 ft HeraGuard ECO. Provides variable work height of 30 to 38 inches in 2-inch increments	50116443
Stand for Clean Bench	Adjustable floor stand for 3 ft HeraGuard ECO. Provides variable work height of 30 to 38 inches in 2-inch increments	50116443
Stand for Clean Bench	Adjustable floor stand for 4 ft HeraGuard ECO. Provides variable work height of 30 to 38 inches in 2-inch increments	50109312
Stand for Clean Bench	Adjustable floor stand for 5 ft HeraGuard ECO. Provides variable work height of 30 to 38 inches in 2-inch increments	50116444
Stand for Clean Bench	Adjustable floor stand for 6 ft HeraGuard ECO. Provides variable work height of 30 to 38 inches in 2-inch increments	50109313
IV Bar	Hanging bar with 6 hooks for 3ft clean bench	50073943
IV Bar	Hanging bar with 10 hooks for 4, 5 or 6 ft clean bench	50073944

Find out more at [thermofisher.com/bsc](https://thermofisher.com/bsc)