Germfree

EXPERT ENVIRONMENTS

# Horizontal Laminar Flow Hood (Z-Series)
# User Manual



# Contents

# Introduction

The Z-Series Hood is designed for the unencumbered and fluid handling of non-hazardous materials in a sterile working environment. The work area is bathed by constant positive pressure horizontal airflow that has passed through a High Efficiency Particulate Air (HEPA) filter. This filter removes organisms and particulates 0.3 micron in size with an efficiency of 99.99%. It is even more efficient for both larger and smaller particles due to the tendency for larger particles to get inertially trapped by the filter, while smaller particles exhibit particle diffusion in the direction of the fiber. The HEPA filter is positioned in the rear of the work area and is protected by a removable, perforated metal diffuser located immediately in front of it. The airflow utilized by the Z-Series Hood consists of moving individual streams of unidirectional, ultra-clean air along parallel lines with minimal turbulence. This airflow pattern is known as laminar.

Your Z-Series Hood is intended to be used as a work area that maximizes product quality control and minimizes risk of product exposure to contaminants. It should only be used with non-hazardous materials since the air being bathed over the product is reintroduced into the environment without being filtered again. The Z-SERIES hood does not provide any protection to the user.

Your Z-Series Hood has been thoroughly tested. The HEPA filter was integrity tested by the filter manufacturer and again at our factory during the assembly process. All testing was performed in accordance with established standards and procedures, including Federal Standard 209 and NSF/ANSI 49.

Contact Germfree Customer Service

+1 386.265.4300

cs@germfree.com

# Installation

The Z-Series Hood should be transported and moved in an upright position. If you have ordered a 24-inch work deck your hood will arrive fully assembled and needs to be carefully uncrated. If you have ordered a 30- inch work deck and indicated to Germfree that you would like the unit shipped partially assembled, please contact Germfree for final assembly instructions. It is very unlikely that your hood will arrive with damage, but if you have any concerns about the quality of the unit, contact Germfree Customer Support (386)-265-4300 immediately.

The 24-inch work deck hood should fit in any doorway 30" wide and 80" tall. The 30-inch work deck will require partial disassembly to fit through a 30" wide x 80" tall doorway.

Once the hood is moved into the laboratory, it should be placed in an area that does not interfere with the air patterns of the room. The air intake is located on top of the unit and should not be disturbed by neighboring equipment, room supply or exhaust filters. Additionally, if there is any window in the room, it should remain closed while the hood is in operation.

If you are unsure where to place the hood, a simple smoke test will help determine the proper location. There should be no turbulent air currents next to, in front of, behind, on top of, or below the hood.
After installation is complete, the Z-SERIES hood needs to be certified by an independent testing organization. This should be done before the unit is placed into service and should be repeated in accordance with the pharmacy board in your state or facility SOPs. Additionally, if the unit is moved to a new location, it should be re- certified.

# Electrical Services

The Horizontal Laminar Flow Workstation can operate at 120v, 60 Hertz. During shipment, the power cord is coiled within the control panel. The plug of the power cord is a NEMA 5-15P and should be connected to the appropriate 3-prong 120v receptacle. For convenience of operations and service, all circuitry is located within the control panel.

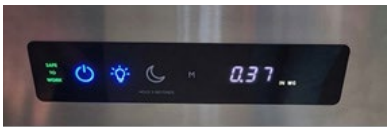
| | Z300 | Z400 | Z600 | Z800 |
|---|---|---|---|---|
| Electrical Configuration | 115V 60Hz | 115V 60Hz | 115V 60Hz | 115V 60Hz |
| Amperage | 2.2 | 2.2 | 2.5 | 2.5 |
| Additional Outlet(s) | 2 Standard Duplex Outlets | 2 Standard Duplex Outlets | 2 Standard Duplex Outlets | 2 Standard Duplex Outlets |
| Power Cord | 10ft.,16 GA-3 wire, 10A | 10ft.,16 GA-3 wire, 10A | 10ft.,16 GA-3 wire, 10A | 10ft.,16 GA-3 wire, 10A |

# Operation

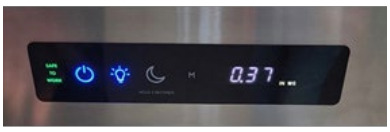
## Control Panel Functions

Flip the switch located on the top of the hood to the on position to allow power into the unit.

Press the icon to power on/off the unit.



When powered on, the Laminar Flow Hood will require a few minutes of startup time. The unit will be safe to use when the "Safe to Work" icon



Press the icon to turn on/off the included LED lamp.

Press and hold the icon for three second to turn on night mode. Night mode will turn on a blue light in the workstation instead of the normal white daytime light. Tap the icon again to turn off night mode.

## Night Mode

- To turn on Night Mode, press and hold the moon icon for 3 seconds. To turn off Night Mode tap moon icon again.
- The unit's LED light will turn blue to visually show the unit is in Night Mode
- Night Mode reduces blower from operational set point to 10% blower speed
- NO compounding should occur in the unit when Night Mode is turned on
- Standard hood cleaning procedures need to be performed after turning Night Mode off and the unit is operating at full blower capacity.
- Night Mode should NOT be used if the facility depends on their hood's to maintain 30 air changes per hour (ACPH).

*Review the use of Night Mode with certifier to ensure regulatory compliance standards are maintained*

# How to Cut the Sealed Data Port for Cables

Cutting a rubber cable port plug with a razor blade requires care to ensure a clean cut and avoid damaging the plug. Here's a step-by-step guide:

**Tools Needed:**

- Razor blade or utility knife
- Ruler or measuring tape
- Marker or pen
- Cutting mat or protective surface
- Safety gloves (optional)
- Safety goggles (optional)

**Steps:**

1. Measure the Cable/Plug Diameter:
    a. Use a ruler or measuring tape to determine the diameter of the cable you plan to pass through the plug.
2. Mark the Rubber Cable Port Plug
    a. Place the plug on a stable surface.
    b. Use the marker to draw an "X" on the plug's surface where you want to cut. Ensure the "X" is slightly larger than the cable diameter to allow for easy passage.
3. Prepare Your Workspace:
    a. Lay down a cutting mat or protective surface to prevent damage to your work area.
4. Cut Carefully:
    a. Hold the plug firmly with one hand. With the other hand, use the razor blade to start cutting along the marked line.
    b. Keep the blade perpendicular to the surface for a straight cut.
5. Test the Fit:
    a. Gently insert the cable through the opening to make sure it fits comfortably without excessive force.
6. Install:
    a. Re-install the rubber cable plug back into the side wall and run desired cables through the cut cable port

**Safety Tips:**

- Always cut away from your body and keep your fingers clear of the cutting path.
- Wear gloves and goggles if you are concerned about sharp edges or flying debris.

# How to Adjust Static Leg Height

These steps detail how to adjust the height of your Z-Series hood unit if you have static legs. Here's a step-by-step guide:

**Safety Precautions:**

- **Top-Heavy Unit:** The laminar hood is top-heavy. Ensure the unit is properly balanced and secure throughout the adjustment process. Use appropriate lifting equipment and assistance if needed.
- **Power Cable:** Protect the power cable during the adjustment process. Avoid damaging it by carefully positioning the lifting equipment. It is recommended to approach the unit from the front.
- **Falling Objects:** Ensure clear space around the unit to prevent accidental injury from falling objects.

**Tools Needed:**

- Lift table cart (1000-lb capacity, 54 1/4" lift)
- 7/16" wrench and/or socket
- Food-grade anti-seize compound
- Rubber mallet
- C-clamps with rubber jaws (Erwin clamps)
- Small Phillips screwdriver

**Steps:**

1. **Prepare the Unit:**
   - Optional: Remove the work deck.
2. **Position the Lift Table:**
   - Center the lift table under the unit.
   - Slowly raise the lift table until it makes contact with the bottom frame, lifting the wheels approximately 1/4 inch off the ground.
   - Secure the unit to the lift table using C-clamps on both sides.
3. **Loosen the Legs:**
   - Loosen and remove the two 14-20 bolts from each leg's crossbar.
4. **Adjust the Height:**
   - Slowly raise the lift table to the desired height. The available heights are approximately:
     - Shipping Height: 32" high at the work deck surface
     - 2nd set of holes: 36" high at the work deck surface
     - 3rd set of holes: 38" high at the work deck surface
     - 4th set of holes: 42" high at the work deck surface
   - If the extension shaft is stuck, carefully tap the crossbar with a rubber mallet to loosen it.
5. **Secure the Legs:**
   - Align one bolt hole to its corresponding hole on the leg.
   - Install one bolt, lock washer, and flat washer, tightening finger-tight.
   - Repeat for the second bolt.
   - Repeat this process for all four legs.
6. **Tighten Bolts:**
   - Tighten all bolts to 12 in/lbs of torque.
7. **Lower the Unit:**
   - Carefully lower the lift table and slide it out from under the unit.
8. **Finalize Positioning:**

Push the unit to its desired location and lock the caster wheels.

# Maintenance

## Prefilters

The prefilter is located horizontally on the top of the unit and should be always kept in place. The prefilter supplied with the unit is a cleanroom rated fiberglass type. Once the unit has been placed into service, the prefilter should be inspected monthly by a certifier. After it has been determined by the certifier how long it takes for the prefilter to load, it should be routinely inspected at this interval to determine if it should be replaced.

Replacement prefilters are available from stock at Germfree. For re-order please see the "Replacement Parts" section of this manual.

Your responsibility as the user of this hood is to keep a log of inspections and replacements of the prefilters.

## HEPA Filters

The average life of a HEPA filter is 3 to 5 years or longer, depending on the cleanliness of the ambient air and the care taken while using the unit. Please note, using Germ free's supplied pre-filters will lengthen the usable lifespan of your HEPA Filter. A loaded HEPA filter cannot be cleaned or recycled. New filters are available from Germfree and we recommend that they be changed by qualified personnel. For re-order, please see the "Replacement Parts" section of this manual.

Your certifier, using R.T.V. silicone sealant, can repair small holes or tears in the filter medium. The filter must be retested for leaks after any repair is made.

The spill guard edge, located at the work surface, will protect the filter from spills on the work surface. If liquid gets over the spill guard, remove the diffuser and carefully soak the liquid up with the edge of a paper towel or any thin material with good absorbency. The filter integrity should be retested by certifier and repaired/replaced if needed. Your responsibility as a user will be to keep a log of certification tests and replacements of your HEPA filters. You will also need to ensure the HEPA filter does not take physical or other compromising damage.

## Motor Blower

The motor blowers were selected because they have the following characteristics: low noise level, low vibration level, compatibility with the variable speed control, and most importantly, the efficiency in delivering air through clean HEPA filters as well as those loaded with a moderate amount of particulate matter.

Before servicing the motors, the power cord must be disconnected or, if this is difficult to reach, the fuses should be removed. For in-depth service repairs please consider using Germfree's service department (386)-265-4300 as your unit may be under warranty. If you are no longer under warranty Germfree can still perform in the field fixes.
It should rarely be necessary to work on the motor blower assembly.

## Filter Diffuser

The HEPA filter is located behind a removable, perforated stainless steel diffuser. Do not push items such as needles through the diffuser holes and do not hang items from any part of the diffuser. Due to the Ultra-clean air passing over the backside of the diffuser, it does not need to be cleaned regularly. The diffuser should only be removed by your certifier, and at that time the backside can be cleaned thoroughly.

During routine cleaning the diffuser will still be attached. Do not spray the diffuser with an aerosol or pump dispenser because you might spray the filter. If an occasional spray mist gets on the filter, it should dry and not cause a problem. The diffuser should be cleaned with a cloth saturated with cleaner. Due to the air pressure coming across the diffuser, any drops that penetrate the diffuser will not come into contact with the HEPA filter. If there is major damage to the diffuser, a certifier should be notified, the filter should be tested immediately, and work should cease inside the hood.

## Optional Equipment

Germfree has simplified our optional equipment, including more standard offerings at a reduced price point bringing more value to our clients.

The only optional equipment is a static stand with working deck heights of 30" or 36" and an electric adjusting stand with work height adjustability from 31" to 38" inches.

Electric lift options are a self-contained system that requires a standard wall receptacle (120V 60hz) power to be operational. No maintenance is required beyond keeping the system clean. Your pharmacy cleaning procedure should not impact the lift system. The lift cylinders are fully sealed.

# Tests and Results

## Airflow Velocity

The outward air velocity is measured across the work deck in accordance with Germfree's test grid located on the data plate of the unit. The velocities are set to be approximately 80-100 fpm average. Velocities when tested on Germfree's test grid fall within 20% of the highest or lowest velocity reading. To assure air velocity does not increase to a point where turbulence may be caused, the motor speed should not be adjusted without assistance from a certifier or industrial hygienist or Germfree service.

## Airflow Patterns

The airflow patterns can be viewed by passing a smoke source in front of the work deck and in directly in front of the HEPA filter and observing the smoke as it exits the work area and is drawn into the top pre-filter of the unit. The smoke should pass directly across the work deck uniform and unidirectional and there should be no ingress/reflux of smoke back into the work deck after exiting.

## HEPA Filter Integrity Tests

The velocities are set to the specified range and the unit is allowed time to flush all ambient particles from the work area. A poly-dispersed, aerosolized DOP is introduced into the upstream filter plenum. A concentration of at least 10 micrograms per liter is introduced. The downstream filter face is then scanned for aerosol penetration. The penetration shall not exceed .01% at any point. The HEPA filters in the Laminar flow hood are rated to be 99.99% efficient.

# Certification / Testing Expectations

Your unit will need to be certified by an independent testing organization when the unit is installed and at least once a year after that for the duration of the hood's operation.

When your unit is first installed, a smoke test should be performed. The certifier can use a smoke tube in the operating room to find the optimal placement locations for the hood. Any turbulent air pockets or inconsistent airflow patterns can be detected by this test.

The hood should be placed in a location with a constant rate and pattern smoke. This test will not be performed after the initial certification unless the airflow in the building has changed, or you plan on moving the horizontal laminar flow hood. During the initial certification, and every year after, two other tests will be performed. The first will be a filter integrity test. The certifier will pump a non-volatile solvent (such as dioctyl phthalate (DOP), polyalphaolefin (PAO) or equivalent) over time into the assembled unit on the upstream side of the HEPA filter. An aerosol photometer will be used to scan the downstream side for any aerosol droplets that might pass through or around the HEPA filter.

The second examination is an airflow test. Using a thermoanemometer or velometer, the certifier will verify that the airflow in the hood is uniform and unidirectional. A thermoanemometer uses a heated probe set in an airstream to determine air speed. The probe determines the heating power required to maintain the high probe temperature. This power is proportional to air speed. Alternatively, the velometer uses a probe that intakes air, and the force against the meter causes a deflection in the needle.

If your pharmacy does not have a certifier, Germfree can assist in finding one in your area.

# Replacement Parts

Germfree wants to make sure that replacement parts do not create down time in your pharmacy, laboratory or cleanroom. Our ordering process is quick and consultative. Please contact our in-house, always human Germfree Customer Service technicians to order the right parts. (386)-265-4300

| Replacement Parts | | Z400 | Z600 | Z800 |
|---|---|---|---|---|
| Pre-Filter | Germfree Part # | 001-1017-00 A | 001-1018-00 A | 001-1017-00 A |
| HEPA-Filter | Germfree Part # | 375-1125-00 | 375-1133-00 | 375-1125-00 |
| Blower Motor | Germfree Part # | 583-4068-00 A | 583-4068-00 A | 583-4068-00 A |
| Touch Screen Control | Germfree Part # | 331-0076-00 | 331-0076-00 | 331-0076-00 |
| LED Light | Germfree Part # | 147-1132-00 | 147-1132-00 | 147-1132-00 |

# Maintenance Schedule

| Maintenance Task | Frequency | Maintenance Completed By | Date Completed |
|---|---|---|---|
| General Cleaning | Determined by Facility SOPs | | |
| Rinse work deck area with fresh water if bleach was used | Discretionary/Specified in SOPs | | |
| Replace Pre-Filters | Discretionary based on visual inspection | | |
| Replace HEPA Filters | Determined by Certifier at 1st Annual Certification | | |
| Hood Re-Certification | Annually | | |

# Cleaning Recommendations

The stainless steel is impervious to most chemicals and can be cleaned with any solvent or stainless steel cleaner. However, if routine cleaning with strong solutions of sodium hypochlorite (bleach) is anticipated, care should be taken to avoid repeated, prolonged exposure of the stainless steel. A thorough rinse using fresh water should be performed following bleach to preserve the stainless-steel finish. The below cleaning reccomendations are recommendation which will not hold precedent over facility or process driven SOPs. Always refer to your facility or process SOP for cleaning your PEC.

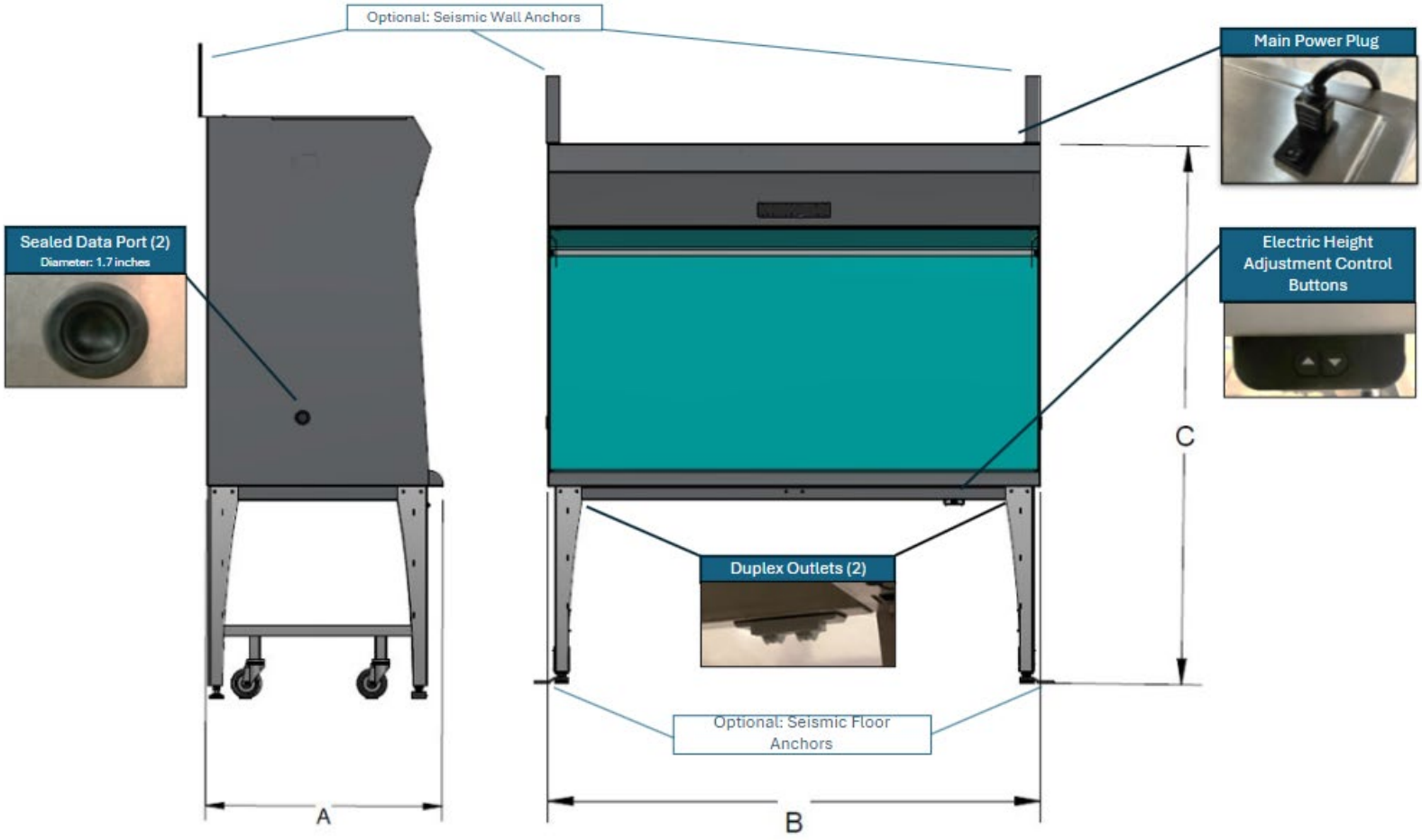
Before entering the secondary engineering control and terminal cleaning:

- Wipe down ALL surfaces in and outside of the hood with a sporicidal disinfectant, EPA-registered disinfectant or sterile 70% iso propyl alcohol using low-lint wipes
- Ensure personnel are wearing gloves
- If using an EPA-registered disinfectant or sporicidal disinfectant, agent must be allowed to dwell for minimum contact time specified by the manufacturer
- If sterile 70% isopropyl alcohol is used, it must be allowed to dry completely

Initial cleaning before working in the laminar flow hood:

1. Prepare: Use lint-free wipes and a sterile disinfectant, such as 70% isopropanol, to remove bacteria, viruses, and fungi. Hoods should be cleaned daily and again if contamination is suspected and after spills. If hood is off, turn the hood on and allow air to blow for 30 minutes.
2. Clean: In the working area inside of the hood, start at the top of the ceiling and work your way down, always in the direction of 'first air'. Do NOT spray cleaning products into the hood. Apply cleaning agent to lint free wipe and clean in the order provided below. A new lint free wipe for each surface that is cleaned.
    - Ceiling: Starting at the back of the hood, wipe left to right moving forward in the direct of first air
    - Back wall: Gently wipe left to right starting at the top working toward the bottom. Do not push hard as it may damage the HEPA filter.
    - Left and Right Sides: Starting at the back, wipe up and down moving forward in the direct of first air
    - **Work surface:** Starting at the back, wipe left to right moving forward in the direct of first air
3. Dry: Let the surfaces air dry completely before starting compounding procedures.

# Dimensional Drawings




| Hood Model | Width (A) | Length (B) | Height (C) |
|---|---|---|---|
| Z300 | 32" | 36" | 78" |
| Z330 | 40" | 36" | 78" |
| Z400 | 32" | 48" | 78" |
| Z430 | 40" | 48" | 78" |
| Z600 | 32" | 72" | 78" |
| Z630 | 40" | 72" | 78" |
| Z800 | 32" | 96" | 78" |
| Z830 | 40" | 96" | 78" |

# Troubleshooting Table

| Trouble | Possible Causes | Remedy |
|---|---|---|
| Air Supply Inoperative | Main switch is off | Check main switch |
| | | Verify plug is in outlet |
| | | Blue light switch should be on |
| No Air Circulation | Blower off | Check motor blower control |
| | Blown fuse | Replace the fuse in the unit main switch. |
| | Break in electrical wiring | Use wiring diagram and check wiring connections |
| Excessive Blower Vibration | Foreign matter in blower squirrel cage | Remove foreign matter |
| Exhaust Air Imbalance | Improper adjustment of blower motor control | Adjust to proper reading on pressure gauge – contact certifier |
| | Obstruction of plenum | Remove obstruction |
| | Leak between blower and plenum | Repair leak – contact certifier |
| | Filter loaded | Replace filter – contact certifier |
| Low Velocity Air | Low voltage on house current | Measure voltage – contact certifier |
| | Filter loaded | Replace filter – contact certifier |
| | Improper adjustment of blower motor | Adjust to proper reading on pressure gauge – contact certifier |
| | Obstruction in plenum | Remove obstruction |
| | Leak between blower and plenum | Repair leak – contact certifier |
| High Velocity Air | Filter rupture | Repair or replace filter – contact certifier |
| | Supply filter gasket leak | Find and repair leak – contact certifier |
| | Exhaust air outlet obstruction | Remove obstruction |
| | Improper adjustment of blower motor speed control | Adjust to proper reading on pressure gauge – contact certifier |
| Non-laminar Airflow | Large object obstructing airflow | Remove item |
| | Large leak in filter | Replace filter – contact certifier |

# Quality Statement

Accountability
We will deliver our products on time, as promised, and free from defects.

Ownership
We will strive to exceed expectations at every level and we will work to make sure that each customer is satisfied with the service that they receive.

Longevity
All of our products are constructed from the highest quality materials and are designed to operate reliably for decades. We stand behind our work and take pride in our superior craftsmanship.

# Our Company

Germfree has been a leading innovator in aseptic control and isolation systems since 1962.

We design and manufacture a diverse range of equipment and facilities for life science applications.

Our systems are integral to critical processes across many sectors. We specialize in complex projects and custom applications that serve the rigorous demands of our clients. Our high-specification bioGO Modular Facilities operate across the world, and are sustainable as permanent facilities in remote regions with harsh conditions.

# Germfree's Mission

Creating Environments that Serve Life Science Innovation and Advance Global Health

Germfree
4 Sunshine Blvd.
Ormond Beach, Florida, USA 32174
+1 386.265.4300

www.germfree.com