

# WHEATON



 **SciLUTIONS**<sup>®</sup> Customized Services



## Receive Exactly What You Want

### Customized Services

Customization, Coordination and Reliability – Offering an integrated suit of services to ensure you obtain the right solution for your needs.

- **Customization** – An expert team of corporate engineers, R&D professionals and integration specialists work collaboratively with you to achieve the solution that meets your needs.
- **Coordination** – The details are our business. We handle all the in-between steps to ensure a smooth and efficient process.
- **Reliability** – Simplify your supply chain and optimize your operations. Long-term solutions ensure our products arrive ready to be used to your standards every time.

We've built our reputation on working with customers by understanding their technologies and processes to provide a solution to meet demanding needs.

For more information on WHEATON Customized Services, contact our customized service solution representative at 800-225-1437 x2768.

**SCiLUTIONS<sup>®</sup>**

## Custom Glass Containers & Package Configuration

### Custom Glass Vials

We've been producing specialty vials such as V Vials® and the E-Z Ex-Traction® high recovery vials for years following the precise instructions of our customers. Think beyond vials, do you need a custom ampule, dropper bottle or serum tubing vial? Almost any product we offer can be customized using our state-of-the-art equipment and manufacturing processes. In addition, WHEATON also has a custom glass hand shop available for one-of-a-kind products.

### Containers Packaged in a Specific Configuration

Our packaging engineers will develop the appropriate packaging to meet your specific needs each and every time with consistent dimensions. We can package containers using your company's materials and shrink-wrap to your specifications.

### Custom Containers

- Engineering and design support
- Custom packaging
- Custom cut glass tubing and rods
- Artwork/decals application

### Manufacturing Processes

- Extrusion Blow Molding
- Injection Blow Molding
- Injection Molding
- Injection Stretch Blow Molding
- Tubular Vial Conversion
- Molded Glass

### Container Materials

- High Density Polyethylene (HDPE)
- Low Density Polyethylene (LDPE)
- Polyethylene Terephthalate (PET)
- Polypropylene (PP)
- Cyclo-Olefin Copolymer (COC)
- Polystyrene
- PTFE
- Type I Borosilicate Glass
- Type III Soda-Lime Glass



## Bar Coding

Bar coding is so much more than a few black bars on a label. The implications bar coding can have on your business are tremendous. From increasing the speed of data collection to eliminating errors that would reduce costs, bar coding gives you the ability to identify and track anything in your lab or compound storage facility. WHEATON can provide bar coding on your glass and plastic bottles and vials, cryogenic vials, plates, tubes or ampules.

It is critical that bar codes are read correctly every time, remain adhered to the container and are durable enough to withstand severe environments. We utilize a variety of symbologies and materials to provide unique identification solutions for biotech, pharmaceutical and compound storage facilities.

WHEATON can customize a bar code solution to meet your specific application. If you need a different material for the bar code, need a specific color to enhance identification or even a different size or shape, the engineers at WHEATON can meet your requirements. From simple pressure sensitive labels to tamper evident bar codes to direct marked containers, our engineers can develop and provide the bar code to fit your application, while guaranteeing no duplicate numbers and sequence integrity.

### Versatile Solutions

A variety of symbologies and materials are available to provide unique identification solutions for biotech, pharmaceutical and compound storage facilities.

- Uniquely numbered and bar coded to fit your application
- 100% scannable
- Choice of symbologies
- Packaged and sequentially numbered to your specifications

### Symbologies

- Code 39
- Code 128
- Interleaved 2 of 5
- 2 Dimensional (2D)
- Dot Matrix

### Materials

- Pressure Sensitive Labels: Label substrate and adhesive
- Ceramic: Imaged ceramic label applied and fired
- Laser: Direct product marked
- Photo Imaging: Ultra high-density, graphically perfect images applied directly to product
- Flexographic: Ink based static printing and label converting, fast drying inks
- Digital: Full process color 1800 dpi, variable data



## Critical Cleaning

We use USP or WFI purified water, HEPA filtering and package items in certified class 100/10 cleanrooms to remove trace organics, trace inorganics, volatile organics and organic carbon residues.

WHEATON can deliver glass containers and accessories with endotoxin levels of less than 0.06 EU/mL with full documentation and certification, and we can provide a special Type I glass vial with a special additive that will prevent the glass from turning brown when gamma radiated.

- Low particulate cleaning
- Depyrogenation, which reduces endotoxin content
- Chemical cleaning for trace analysis
- Sterilization (E-beam and gamma irradiation, autoclaving, dry heat)
- Water for Injection (WFI) rinse (or cleaning)
- USP Purified Water Rinse
- Total Organic Carbon (TOC) Process
- Class 1000: Container and closure without washing treatment
- Class 2000: Container and closure cleaned and assembled
- Class 3000: Container and closure cleaned, assembled and quality assurance analyzed

## List of Certifications Available

- Certificate of Analysis, TOC
- Certificate of Analysis, Endotoxin
- Certificate of Analysis, Particles
- Certificate of Process
- Certificate of Sterility/USP
- Certification of Compliance
- Selected Testing by USP Methods
- Materials Certification

## Custom Packaging Configurations

- Individual or multi-unit clean room bags
- Single or double bagged
- Autoclaved bagging in clean room bags (closures only)
- Autoclaved bagging (single, double or triple bagged)
- Anti-static tray pack with shrink-wrap

In order to provide you the best service possible, contact WHEATON early in the process to see what steps we can remove from your process to save you valuable time and money.



## Surface Deactivation Treatment

Surface treatment refers to a process by which the entire surface of a container is deactivated via silanization or siliconization. The coating provides a protective barrier between the contents and the glass, eliminating active sites on the glass that could potentially react with its contents. Using vapor phase deposition for silanization or siliconization coating to lubricate and protect against alkalization, we ensure containers are properly prepared for your procedures. Siliconization is ideal for serum vials and containers used to store pH sensitive samples.

Silanized vials are used to reduce the adsorption of polar compounds onto the surface of the glass container. It also helps to avoid alkalization of contents, which may occur as carbonates leach from the glass with normal "weathering". Autosampler vials treated with silanization improve sample recovery. WHEATON frequently silanizes vials and vial inserts for customers using analytical techniques.

## Silanization and Siliconization

Provides a protective barrier between the contents and the glass, eliminating active sites on the glass that could potentially react with its contents.

## Serum Vials and pH Sensitive Storage

Silanization lubricates the vial and protects against alkalization.

## Certificates of Conformance

Available based on customer requirements.



## Taring – Pre-Weighed Containers

SciLutions® customized services can provide you with pre-weighed containers. Taring ensures that the amount of material in the container can be accurately measured at any given time.

WHEATON is proud to offer this service, eliminating the extra step of pre-weighing in the lab. Weights for each container are recorded to the accuracy of  $\pm 0.2$  milligrams. The results are summarized in the form of a spreadsheet allowing for each and every container to be fully traceable. This spreadsheet can accompany the product and/or be sent independently via email. Bar coding is recommended when taring for proper weight identification.

### Eliminate extra steps in the lab

- Pre-weighed containers
- Traceability documentation
- Accuracy to  $\pm 0.2$  milligrams



## Container Terminology

### Cyclo-olefin Copolymer (COC)

Cyclo-olefin copolymers are a family of amorphous, transparent copolymers based on cyclo-olefins and linear olefins. Performance characteristics of cyclo-olefins include low density, excellent transparency, low water absorption, excellent vapor barrier properties, heat deflection temperatures up to 170°C, excellent bio-compatibility and chemical resistance. Poor gas barrier properties. Sterilizable via radiation and certain grades can be steam autoclaved.

### Extrusion Blow Molding

A molding process whereby heat-softened polymer is forced into the shape of a hollow tube. While still soft, a mold closes around the tube, pinching the top and bottom of the tube closed. A Blow Pin is introduced and air is forced through the pin forcing the tube to take the shape of the Blow Mold cavity.

### Finish

The part of the bottle or vial that holds the cap, stopper or closure. This part of the finish, whether a serum or screw thread, is commonly called the "T" dimension.

### Injection Blow Molding

A molding process in which heat-softened polymer is injected from a Plastifier into a mold cavity creating a Preform, which is then transferred to a Blow Mold where air is blown into the Preform, forcing it to take the shape of the Blow Mold cavity.

### Injection Molding

A molding process whereby a heat-softened polymer is injected from a Plastifier into a relatively cool cavity, which gives the article the desired shape.

### Injection Stretch Blow Molding

A molding process whereby Preforms are introduced into a cavity, stretched axially by a Stretch Rod and then blown circumferentially to the shape of the Blow Mold cavity.

### High Density Polyethylene (HDPE)

Flexible but more rigid than LDPE. Natural color is milky white, semi-translucent depending on density. Good impact strength and stress crack resistance. Good chemical resistance. Good vapor barrier but poor gas barrier properties. Sterilizable via Ethylene Oxide or Gamma radiation.

### Linear Coefficient of Expansion

The fractional change in length of a piece of glass per degree change in temperature. The coefficient of expansion generally indicates the thermal endurance of the glass. Glasses with low linear coefficient of expansion are more resistant to thermal shock than glasses with a high coefficient of expansion.

### Low Density Polyethylene (LDPE)

Very flexible, natural milky color, translucent with high impact strength. Excellent for mild and strong buffers, good chemical resistance. Good water vapor and alcohol barrier properties. Poor gas barrier properties, sterilizable with ethylene oxide or gamma radiation. Good stress crack resistance.

### Polyethylene Terephthalate (PET)

Semi-rigid to rigid depending on wall thickness. Natural color – clear and transparent. Good alcohol and solvent barrier; good gas and fair moisture barrier. Good to fair chemical barrier; not good for strong acids or bases. Good moldability. Sterilizable through ethylene oxide or gamma radiation. Good stress crack and impact resistance at room temperature and above.

### Polypropylene (PP)

Rigid, solid and durable in container or cap forms. Excellent stress crack and impact resistance. Excellent moisture barrier, good oil and alcohol barrier, poor gas barrier properties. Good chemical resistance. Sterilizable with ethylene oxide or autoclaving.

### USP Type I, Class A

USP Type I classification refers to borosilicate glass with superior chemical resistance representing the least reactive glass containers available. Type I glass may be used to package acidic, neutral and alkaline products, as well as water for injection, unbuffered products, chemicals, sensitive lab samples and those requiring sterilization. Type I glass can be subject to chemical attack under certain conditions including very low and very high pH applications.

### USP Type III

USP Type III is a soda lime glass with moderate chemical resistance used primarily for general storage applications. Type III glass may not be suitable for autoclaved products because the autoclaving process will accelerate the glass corrosion reaction. Dry heat sterilization is not a problem for these containers.



## Critical Cleaning Terminology

### Depyrogenation\*

Pyrogens are fever producing substances. The FDA is primarily concerned with endotoxins. Endotoxins are found in certain bacteria, and if present in an injection can cause a range of symptoms and possibly lead to death. Depyrogenated products have reduced endotoxin content by 99.9% or 3 logs. Depyrogenation includes dry heat treatment to destroy the pyrogens and multiple WFI rinses to remove the pyrogens. (Certifications: Certificate of Process, Certificate of Analysis).

### E-beam Irradiation Sterilization

E-beam sterilization uses an E-beam generator (between 1 MeV and 12 MeV) to produce a beam of high energy electrons that destroys organisms by breaking the chains of DNA in living organisms, such as bacteria, resulting in microbial death and rendering the space they inhabit sterile.

### Ethylene Oxide (EtO) Sterilization

Ethylene oxide gas kills bacteria and their endospores, mold and fungi, and can therefore be used to sterilize substances that would be damaged by sterilizing techniques that rely on heat. Gas is commonly used to sterilize objects sensitive to temperatures greater than 60°C. Ethylene oxide treatment is generally carried out between 30°C and 60°C with relative humidity above 30% and a gas concentration between 200 and 800mg/L for at least three hours. Ethylene oxide is the most common sterilization method, used for over 70% of total sterilizations, and for 50% of all disposable medical devices.

### Fluorination

Fluorination of plastic containers prevents container distortion and reduces chemical permeation, weight loss and odor emission.

### Gamma Irradiation Sterilization

Gamma rays are produced from a Cobalt (Co60) source and have a high penetrating power. Applying this radiation dose (typically 25-40kGy) is sufficient to destroy all viable forms of life, including bacterial spores, to an acceptable sterility assurance level (SAL). The products that typically receive this treatment are glassware, stoppers, seals, certain caps and plastic bottles. Components must be radiation stable. Clear glass (USP Type I) will discolor. (Certifications: USP Sterility, Certificate of Process).

### Low Particulate\*

High purity electronics grade water, filtered to sub-micron levels, is used to wash containers, removing all particulate. This processed water not only meets, but far exceeds all criteria specified by the USP for Purified Water and Water for Injection Rinse (WFI Rinse) depending on the size of the container. (Certifications: Certificate of Process).

### Steam Sterilization (Autoclave)\*

The application of steam, heat and pressure to destroy all viable forms of life, including bacterial spores, to an acceptable sterility assurance level (SAL). Steam sterilization is attained at a temperature of 121°C, a pressure of 15 psi, and an exposure time of 30 minutes minimum. Typically a SAL of 10<sup>-6</sup> is required; probability of a non-sterile unit is greater than one in a million. The products that typically receive this treatment are glassware, stoppers, seals, certain caps and polypropylene bottles. (Certifications: USP Sterility, Certificate of Process).

### Sterile Foil Wrap\*

Sterile foil wrap process is a method for producing a sterile/depyrogenated product through exposure to dry heat. This process is used mainly for small vials. The vials are particulate cleaned, dried in Class 10 HEPA filtered dryers, wrapped in multiple layers of clean room grade aluminum foil and baked at 250°C in a depyrogenation oven for a minimum of 2 hours and 45 minutes. Once cool, foil packs are removed from the oven, placed into polypropylene trays, shrink wrapped and double clean room bagged. The vials are never exposed to non-sterile conditions after they are sterilized. (Certifications: Certificate of Analysis- Endotoxins, USP Sterility, USP Particulates).

### TOC (Total Organic Carbon)

Cleaning containers for Total Organic Carbons testing. This process is done outside of the cleanroom environment and is not used in conjunction with USP/WFI rinses. This process uses very high temperatures (500°C). TOC products have reduced TOC levels to 10-20 ppb. (Certification: Certificate of Analysis- TOC).



## Surface Deactivation Treatment Terminology

### Ammonium Sulfate Treated Glass

All glass contain alkali metal ions, particularly sodium. These ions will tend to have increased concentration at the surface of the glass. Surface tension is the driving force since the energy of the glass would be reduced with this higher concentration. Aqueous products can react with these ions, causing them to be extracted into the product, which may cause an increase in pH for most neutral/acidic solutions. "Sulfur" treated glass takes advantage of this fact by pre-reacting the glass surface and exchanging these surface alkali with hydroxyl groups before product packaging. The surface, after treatment and washing, becomes depleted in alkali. These ions are no longer available for extraction, and the apparent durability properties of the glass are improved. (Certification: Certificate of Conformance).

### Silanization

A methylsilylating agent is introduced by vapor phase deposition onto the surface of the disposable glassware. This method deactivates the glass surface by reducing surface tension and preventing non-specific binding, allowing for maximum recovery of trace analyte. This procedure works well for treating vials and inserts for use in analytical methodologies. (Certification: Certificate of Conformance).

### Siliconization

A coating that provides lubrication and protection against alkalization. This treatment works well for serum vials and pH sensitive storage applications. It is a method of deactivating a surface by reducing surface tension and preventing non-specific binding. (Certification: Certificate of Conformance).

The internal Siliconization of glass vials has three advantages. It further minimizes the interactions between the product and container. It prevents high viscosity products from sticking to the internal surface of the vials giving the glass bottle a perfect transparency. Finally, due to its hydrophobic properties, the silicone coating ensures a higher restitution rate down to the last drop of the product.



## Taring – Pre-Weighed Containers Terminology

### Gross Weight

Total weight of container and contents.

### Inert Glovebox

Custom benchtop enclosure, airtight and purged with nitrogen or argon so that weighing can be performed in a moisture-free environment for greater accuracy. Containers, caps, scales and computers are all handled within the enclosure via gloves mounted to the cabinet.

### Net Weight

Gross weight – tare weight = net material weight.

### Tare Weight

Weight of the empty container, with or without cap.

\* 100/10 Cleanrooms

\* Class 100 process area with Class 10 packaging



## Bar Coding Terminology

### 2 Dimensional (2D) Bar Codes

A machine readable symbol of rows of encrypted data arranged in a rectangular or square pattern. Can store large amounts of text, numbers, extended & Unicode® characters or photos, making them a much better option for very large amounts of data storage.

#### Alphanumeric

Character set that consists of upper and lower case letters, numbers 0 through 9 and characters such as the dollar sign, plus, minus, period, comma and other special characters.

#### Bar Code

A series of black bars and light spaces that are used to represent letters and/or numbers. The bars have varying width and arrangements in order to represent different characters.

#### Ceramic Marked

Imaged ceramic label applied and fired. Extremely durable and will not lose weight over time.

#### Code 39

If you are making a general-purpose system that needs to read only numbers and uppercase letters, you can use Code 39. A variable length, bi-directional, self-checking, alpha-numeric linear bar code. It contains 0 through 9, capital letters A through Z, minus symbol, plus symbol, forward slash, space, decimal point, dollar sign and percent symbol. Each character is encoded by 9 bars, 3 of which are always wide.

#### Code 128

For general-purpose use, Code 128 is usually the best choice. A variable length, bi-directional, continuous, self-checking, alphanumeric linear bar code. Characters in Code 128 consist of 3 bars and 3 spaces with a total character width of 11 modules. It can encode the full 128 character set.

#### Data Matrix

A very space-efficient 2D symbology that uses a unique perimeter pattern that helps the scanner determine cell locations. The cells are made up of square modules. It can encode letters, numbers, text, bytes of data, extended characters, unicode characters and photos.

#### Digital Marked

Full process color, 1800 dpi, variable data.

#### Flexographic Marked

Ink based static printing and label converting.

#### Interleaved 2 of 5

For barcoding numbers only, use Interleaved 2 of 5. This symbology has the flexibility to encode any even number of digits. A continuous, self-checking, numeric symbology linear bar code. It consists only of the numeric values 0 through 9.

#### Laser Etched

Direct product marking using a high powered laser to burn away the surface coating on a product.

#### Linear Bar Codes

Black and white vertical bars located on the side of the container. Contains various amounts of data ranging from simple number chains to large amounts of numeric and alphanumeric data sets.

#### Photo Imaging Marked

Ultra high-density graphically perfect images.

#### Symbology

Term used to describe how information is encoded into the physical attributes of the bars and spaces. It is the set of rules for a particular type of bar code; analogous to language.

#### Thermal marked

Ribbon based printing 200-600 dpi. Pressure sensitive labels capable of holding up at - 196°C and exposure to various chemicals including DMSO, methanol, isopropyl alcohol, etc.

### Bar Code Formats

- **Pressure Sensitive Labels:** A pressure sensitive label that consists of a label substrate and adhesive designed to form a bond with a smooth surface and hold securely at room temperature.
- **Laser:** Permanent bar code is laser etched directly onto the product.
- **Ceramic:** Bar code is applied to a ceramic label, then the product is fired. Extremely durable and will not lose weight over time. Ideal in environments with strong caustics, acids or temperature extremes.
- **Photo Imaging:** Ultra high-density, graphically perfect images are applied to the product.
- **Flexographic:** Bar code printing using flexible printing plates made of rubber or plastic. The inked plates with a slightly raised image are rotated on a cylinder that transfers the image to the substrate. Flexography uses fast-drying inks. It is a high-speed print process that can print on many types of absorbent and non-absorbent materials and can print continuous patterns.
- **Digital:** Bar code is produced using full process color 1800 dpi, variable data printing.

Because it's my life's work...



## WHEATON

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