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**STERILE / DEPYROGENATION  
 OF GLASSWARE**

**CRITICAL ENVIRONMENT APPLICATIONS**

C & G Containers, Inc. (C & G) provides a product line of Depyrogenation procedures on selective glassware and glass components by validated dry heat methodology. C & G Containers accepts and can process "standard" type glassware containers or customer "supplied" glassware. The product undergoes an initial water cleaning step using C & G's purified water system which exceeds the criteria in meeting USP specifications for purified water. After this initial wash step and drying is complete, the product is wrapped in a sterile foil multiple times and placed in a Depyrogenation oven and baked at a minimum of three (3) hours at the required temperature. (A Certificate of Process and process chart is provided for every order) The product is removed after product reaches 40° C or lower and placed into its final packaging of two "Clean Room" bags and shrink wrapped for further assurances of outside contaminants exposure. Products are boxed appropriately and labeled for content(s) identification. Sterility and traceability is maintained through out the sterility steps.

**Applications include:**

| <b>PARENTERAL</b> | <b>NON PARENTERAL</b>   |
|-------------------|---|
| Injectables       | Sampling & testing for Endotoxins   |
| Stability Studies | Reagent & Chemical storage under multiple uses as aseptic applications are required |
| Clinical trials   | -   |

**Quality Assurance**

- ⊖ A Certificate of Process is provided for each Lot of glassware
- ⊖ A Cleaning protocol form is provided for each lot of process
- ⊖ A circle recording chart of the process is initiated and can be provided

**Quality Control**

- ⊖ Clients or each manufacturing component's identification or lot number(s) is traceable to C & G's selected Lot # for complete traceability
- ⊖ All temperatures and processes are monitored as part of C & G's Performance Based Specifications

**Benefits of using C & G Critical Environment Products**

- ⊖ Cost savings due to outsourcing rather than "in-house" production
- ⊖ Reduce or eliminate capital equipment expenditures for this process
- ⊖ Reduction of labor
- ⊖ Ready to use products on hand

**ORDER INFORMATION BY QUOTE: Contact: Robert Greer (417) 782-3314**