

DEPYROGENATION/STERILIZATION

CERTIFICATE OF PROCESS

PRODUCT ITEM #: _____

DATE PROCESSED:___/__/___

LOT #:

<u>PROCESSED SUMMARY</u>: Each piece of glassware is processed through the C & G's Protocol B¹ wash procedures and dried at 260° F. The glassware is allowed to cool to approximately 70° F. Each individual piece of Glassware is encased in clean aluminum foil. A second wrap of aluminum foil is place over the first layer of aluminum foil securing any openings. Each piece of glassware is process treated at 842°F / 450°C with confinement for two (2) hours. The product is allowed to cool to ~ 70 ° F and placed in two separate clean room bags and tied off. A label is attached to the outside of the second clean room bag. A compliance chart recorder registers the time and temperature to ensure the procedure is followed while meeting the required specifications.

Compliance Verification of Process:

Date

Bo Blankfield Technical Director

¹Protocol B Procedure for Closures: Jet rinsed with ASTM Type 1 Water