



Sales Order: #####  
Purchase Order: #####  
Model #: #####  
Lot Number(s): #####  
Shipment Date: #####

This is to certify that the products shipped with this Sales Order conform to Equilibar standards and to the client’s specifications.

**Certificate of Material Conformance:**

**Equilibar Model#**

**Lot Number(s):**

Body Material: USP Class VI HDPE Resin – ##### (See attached MTR)

Diaphragm: USP Class VI HDPE - ##### (See attached MTR)

**Certifications:**

These products were inspected, welded, tested, and double bagged in an ISO Class 7 clean room and conforms to Equilibar’s manufacturing SOP.

*USP<85> Endotoxin tests are sampled on a by-lot basis according to USP <85> procedures with a 20 EU/device limit.*

LAL Endotoxin Test Results – See attached

*USP<788> Particulate tests are sampled on a by-lot basis according to USP <788> procedures with the following limits:*

*≤ 25 Particles / mL for ≥ 10 µm Particle size*

*≤ 3 Particles / mL for ≥ 25 µm Particle size*

Particulate Test Results – See attached

*Shelf Life*

Contact Equilibar for details on shelf-life testing.

*Sterilization/Irradiation*

These valves have an ionizing radiation compatibility range of 0 – 50 kGy

These valves are not rated for autoclave sterilization.

*Extractables / Leachables USP <665>*

Contact Equilibar for details on USP <665> / BPOG extractables testing.

**ADI/TSE/BSE Free Statement:**

Equilibar has reviewed the components used in the regulators included in this order for TSE/BSE risk.

We have confirmed that the machined metal components that may come into direct contact with the process media have been manufactured without the use or involvement of raw materials of animal origin, including animal proteins. The polymers or rubbers used in this product have been provided from suppliers with TSE statements.

We confirm that these regulators have not come into contact with raw materials of animal origin during production or handling at Equilibar.

The above information reflects Equilibar’s current knowledge based on supplier information and Equilibar process quality controls. The statement is subject to change if new information becomes available.

**BPA Free Statement:**

Equilibar has reviewed the raw materials used in production of the wetted regulators for this order and certifies that there is no known Bisphenol A product used in any polymer resin during the manufacture of this product, according to the resin manufacturers.

Liability: Equilibar, LLC does not accept any liability with respect to the use of this information nor the application, adaptation or processing of the product described herein.

Signed \_\_\_\_\_ Date: \_\_\_\_\_  
#####  
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