



Documentation

A Certificate of Compliance to material (with heat number for body and ferule), surface finish and FDA USP Class VI is provided for each line item on all Steriflow orders at no charge (see example below).

STERIFLOW
A DIVISION OF JORDAN VALVE

3170 Wasson Road, Cincinnati, Ohio 45209
(513) 533-5600 - Toll Free (800)-543-7311 - Fax (513) 871-0105

CERTIFICATE OF COMPLIANCE

• **ORDER INFORMATION:**
Customer Name: XXXXXX ENGINEERED SYSTEMS INC
PO Number: 1456-SENT-1 Factory Order No.: 200XXXX
Order Date: 12/7/09

• **CERTIFICATION OF MATERIAL COMPLIANCE:** Traceable material certification and MTC's for this order are attached to this document.

• **CERTIFICATION OF SURFACE FINISH:** The interior, wettable surfaces of the valve bodies furnished on the above referenced order have a minimum surface finish of 20Ra µin (5.1µm) and the exterior, non-wettable surfaces have a maximum surface finish of 80 RMS.

Wettable components are certified to be electro-polished.

Note: The above statement does not apply to models CGDM, or USD1, or Sample Cooler or Sight Glass models without EP order code option. The model MK30 body is not electro-polished as standard.

• **CERTIFICATION TO FDA & USP CLASS VI:** STERIFLOW by Jordan Valve certifies that the WETTED elastomer, Teflon, PTFE-resin and perfluoropolymer compounds utilized in our sanitary products have been manufactured in accordance with prescribed procedures for pharmaceutical products and have been tested and certified to be in compliance with:

- Title 21, Paragraph 177.1350 of the FDA Code Federal Regulations for plastic materials for repeated use in contact with food.
- Title 21, Paragraph 177.2600 of the FDA Code Federal Regulations for rubber and rubber-like materials for repeated use in contact with food.
- U.S. Pharmacopeia XXVIII Class VI Section 88 Biological Reactivity Test in Vivo.

The following materials used in Richards Industries Steriflow Products are certified to FDA and USP Class VI per the following:

Diaphragm Materials
FDA APPROVED MATERIAL **FDA and USP VI APPROVED MATERIAL**
 EPDM/NYLON JORLON
 TFE-VITON

O-ring/Gasket Materials
FDA APPROVED MATERIAL **FDA and USP VI APPROVED MATERIAL**
 BRUNA-N TFE-SILICON TEFLOX
 TFE-VITON TUF-STEEL™
 KALREZ SILVERBACK™
 EPDM
 SILICONE
 VITON
 JORLON
 FLEXORAZ

Seat Materials
FDA and USP VI APPROVED MATERIAL
 TFE PEARLAST™
 JORLON TFM 1600
 TEFLOX

We certify that the components on the above referenced purchase order meet the requirements of the purchase order, applicable drawing(s) and our ISO 9001:2008 manufacturing, testing, and inspection procedures to assure an acceptable quality level applicable to the product.

Exhibit 278 Date Issued: 5/2/07 Date Revised 8/3/09 Part Number 20242

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TRACEABLE MATERIAL CERTIFICATION (PRESSURE CONTAINING PARTS)

Tag #

| Item | Quan. | Value | Description | Material Type, Spec, Size | Heat # |
|------|-------|----------------|-------------|---------------------------|---------------|
| A | 2 | 976SP-075-ID-T | BODY | UNS S31600 / S31603 | ER1632 |
| | | | FITTING | UNS S31603 | 420576,418167 |

Tag #

| Item | Quan. | Value | Description | Material Type, Spec, Size | Heat # |
|------|-------|-------|-------------|---------------------------|--------|
|------|-------|-------|-------------|---------------------------|--------|

Tag #

| Item | Quan. | Value | Description | Material Type, Spec, Size | Heat # |
|------|-------|-------|-------------|---------------------------|--------|
|------|-------|-------|-------------|---------------------------|--------|

Quality Manager: *[Signature]* Date: 1/13/2010

• THE ATTACHED MATERIAL CERTIFICATIONS ARE FOR MATERIALS USED IN THE MANUFACTURE OF THIS ORDER. IN THE CASE OF DUAL-CERTIFIED MATERIALS, REFER TO THE PROPERTIES TO VERIFY CERTIFICATION.

We certify that the components on the above referenced purchase order meet the requirements of the purchase order, applicable drawing(s) and our ISO 9001:2008 manufacturing, testing, and inspection procedures to assure an acceptable quality level applicable to the product.

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The following additional, individual documentation is available from our factory upon request at time of ordering:

- Traceable Material Certificates
- FDA Certificates on soft seals
- USP Class VI seal materials upon request
- Jorlon diaphragm USP Class VI <88> in vivo testing, and USP <87> in vitro certificate of compliance
- ADI (Animal Derivative Ingredient) and TSE (Transmissible Spongiform Encephalopathy) free certificate of compliance
- Final Test Reports
- Certificate of Surface Finish
- Certificate of Compliance/Certificate of Origin

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