

## Saunders<sup>®</sup> Industry Conformance Life Science Diaphragms

[www.cranecpe.com](http://www.cranecpe.com)

### Industry Conformance

Saunders<sup>®</sup> portfolio of diaphragms for bio-process applications has been specially developed and manufactured specifically for the unique demands of this market segment. Conformance to industry regulations is as critical as reliability and performance for our customers in the BioPharm industry. Saunders<sup>®</sup> Life Science Diaphragms meet all applicable industry standards and regulations, including:

**FDA CFR Title 21 177.2600 (rubber articles)**

**FDA CFR Title 21 177.1550 (perfluorocarbon resins)**

These regulations define which ingredients can be used in the formulation of rubber (elastomer) and perfluorocarbon (PTFE) components that contact drug products.

Saunders<sup>®</sup> Life Science Diaphragms have been third party tested in accordance with United States Pharmacopeia (USP).

**USP Class V and VI, <87>, <88>**

These USP tests measure the safety of polymeric materials. USP <87> is an in vitro test that measures extractables from elastomeric plastics. USP <88> is vivo test that measures biological reactivity of mammalian cell culture following contact with elastomeric plastics.



Saunders<sup>®</sup> Life Science Diaphragms:

- 1 Comply with ASME BPE, Part SG. This portion of the BPE Standard defines requirements for design, marking, testing, and seal performance
- 2 Animal Derived Component Free (ADCF), certified phthalate free and PFOA free
- 3 Are lot traceable to EN 10204 3.1

FDA, USP, and Traceability Certificates of Compliance are available on request.



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## Elastomer Diaphragms

- Grade ER Peroxide Cured EPDM
- Grade 500 Dicumyl Cured Silicone
- Grade PV Passivation Diaphragm Peroxide Cured EPDM Special P Style Attachment Passivation Duty Only

## PTFE Diaphragms

- Grade PR PTFE Face Peroxide Cured EPDM Backing
- Grade SR Modified PTFE Face Peroxide Cured EPDM Backing
- Grade EX – Endurance Diaphragm Modified PTFE Face Dicumyl Cured Silicone Backing

## Product Features

All Saunders® Life Science Diaphragms are developed and manufactured in-house

## Typical Applications

Compendium waters, process, CIP, SIP Compliance  
FDA, USP Class VI <87>, <88>, ASME BPE, EN 1093

Please visit our Web-Based Drawing Library at: [www.saundersdrawings.com](http://www.saundersdrawings.com) for current database of drawings in PDF, 2D DWG, and 3D STP formats.



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