

Saunders[®] Industry Conformance Life Science Diaphragms

Industry Conformance

Saunders[®] 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[®] 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[®] 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[®] 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.

Elastomer Diaphragms

- Grade 425 Peroxide Cured EPM
- Grade 425 Peroxide Cured EPM, Post Cured
- Grade EE Peroxide Cured EPDM
- Grade EF Peroxide Cured EPDM, Post Cured
- Grade 500 Dicumyl Cured Silicone
- Grade PV Passivation Diaphragm Peroxide Cured EPM Special P Style Attachment Passivation Duty Only

PTFE Diaphragms

- Grade 214S/425 Modified PTFE Face Peroxide Cured EPM Backing
- Grade 214S/EE Modified PTFE Face Peroxide Cured EPDM Backing
- Grade 214/425 PTFE Face Peroxide Cured EPM Backing
- Grade 214/EE 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 for current database of drawings in PDF, 2D DWG, and 3D STP formats.



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