919-981-6584
877-371-7264
info@diaphagmdirect.com
www.diaphragmdirect.com

DIAPHRAGM® DIRECT

Diaphragm Direct®
Bio-Pharma Diaphragms

Grade E7 EPDM Diaphragm

Diaphragm Direct® Grade E7 EPDM diaphragm was developed specifically for critical applications of the Biopharmaceutical Industry. It has been developed and extensively tested at our in-house development laboratory and third-party tested at The BioProcess Institute.

GRADE: E7

MATERIAL: Ethylene Propylene Diene Monomer - (Peroxide Cured)

SIZE: ¼"–6" (DN6 - DN150)
Please consultant factory for availability.

TEMPERATURE RATING:
-40 to 110° C Liquid Media
-30 to 150° C Max Steam Sterilization (max 180 minutes per cycle)

REGULATORY COMPLIANCE:
- FDA 21 CFR 177.2600
- USP Class VI, <87>, <88>
- ISO 10993-5, -6, -10, -11
- ASME BPE part SG
- Certified Animal Derived Ingredient Free EMEA /410/01 TFE/BSE
- Fully lot traceable to EN 10204 3.1

KEY FEATURES INCLUDE:
Improved resistance to steam, WFI and commonly used CIP chemicals, buffers, protein solutions and other products. Fabric reinforced to provide full support for the elastomer face and to increase flex performance. Peroxide cured for optimum cross linking performance and to minimize extractables and leachables. Reduces the need to re-torque and assures seal integrity. Enhanced surface finish integrity to assist process purity (ASME BPE compliant).

Successfully tested per the 100/500 SIP Study for Diaphragm Valve Diaphragms (ASME BPE Appendix J.1.2.1)
60 Minute SIP Cycle, as tested in The BioProcess Institute's BioProcess Performance Reports®. (BPPR®).

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Grade E7 EPDM Diaphragm

CONSTRUCTION:

- Grade E7 EPDM
- Organic Peroxide cured
- Excellent resistance to compression set
- Excellent mechanical and thermal properties
- Fabric reinforced to optimize flex

DIAPHRAGM TRACEABILITY

All diaphragm materials and physical properties are batch traceable with permanent codes molded onto the diaphragm. Molded information includes: Manufacturing Date/Cure Date, material grade, and diaphragm size.

All Grade E7 EPDM Diaphragms have High Performance Woven Fabric Reinforcement

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Diaphragm Direct®
Bio-Pharma Diaphragms

TFM™ (PTFE)/EPDM Diaphragm

Diaphragm Direct® TFM™ (PTFE) backed EPDM (Grade E7) diaphragm was developed specifically for the critical process protocols and applications of the Biopharmaceutical Industry. It has been developed and extensively tested at our in-house development laboratory and third-party tested at The BioProcess Institute.

GRADE: TFM™ (PTFE) backed EPDM

MATERIAL: Modified PTFE (TFM™) with Ethylene Propylene Diene Monomer - (Peroxide Cured) backing

SIZE: ¼"–6" (DN6 - DN150)

Please consultant factory for availability.

TEMPERATURE RATING:
-34 to 176º C (-30 to 350º F)

REGULATORY COMPLIANCE:
- FDA 21 CFR 177.1550 (a)
- FDA 21 CFR 177.2600 (Backing cushion)
- USP Class VI, <87>, <88>
- ISO 10993-5, -6, -10, -11
- ASME BPE part SG
- Certified Animal Derived Ingredient Free EMEA /410/01 TFE/BSE
- Fully lot traceable to EN 10204 3.1

KEY FEATURES INCLUDE:
Improved resistance to SIP and CIP chemicals, Compendium waters, buffers, protein solutions and other products. Ideal for applications subjected to intermittent steam service. The EPDM backing is Fabric reinforced to provide full support for the elastomer and to increase flex performance. The EPDM backing is peroxide cured for optimum cross linking performance and to minimize extractables and leachables. Enhanced surface finish integrity to assist process purity (ASME BPE compliant).

Successfully tested per the 100/500 SIP Study for Diaphragm Valve Diaphragms (ASME BPE Appendix J.1.2.1) 60 Minute SIP Cycle, as tested in The BioProcess Institute's BioProcess Performance Reports®. (BPPR®).

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Diaphragm Direct®
Bio-Pharma Diaphragms

TFM™ (PTFE)/EPDM Diaphragm

GRADE TFM™ (PTFE)

TFM™ offers several enhancements over conventional PTFE:

- optimum ratio of crystalline and amorphous micro-structure
- Reduced creep and cold flow at elevated temperatures
- Greater dimensional stability
- Greater crack resistance
- Reduced permanent deformation under cyclic load
- Enhanced surface finish integrity to assist purity

MATERIAL (2-PIECE CONSTRUCTION)

- TFM™ grade PTFE wetted face offer the widest temperature range of any polymer. TFM™ grade PTFE is inert to corrosive chemicals, has improved cleanability due to reduced permeation, reduced voids, pore free surface, and has excellent anti-stick properties.
- E7 grade (organic peroxide cured) EPDM backing cushion offers excellent mechanical and thermal properties, excellent resistance to compression set, and is fabric reinforced to optimize flex.

DIAPHRAGM TRACEABILITY

All diaphragm materials and physical properties are batch traceable with permanent codes molded onto the diaphragm. Molded information includes: Manufacturing Date/Cure Date, material grade, and diaphragm size.

TFM™ (PTFE) offer improved sealing and flex life. All Grade E7 grade backing cushion have high performance woven fabric reinforcement.

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Diaphragm Direct®
Bio-Pharma Diaphragms

Validation & Compliance

The Pharmaceutical and Bioprocessing industries are governed by stringent process validation and maintenance protocols. Diaphragm Direct® recognizes the importance of these stringent requirements and offers a complete selection of documentation to facilitate the validation process. Diaphragm Direct® offers traceability and transparency in the entire manufacturing process of its diaphragms.

- Physical properties, raw materials, compounding and molding process are documented
- Diaphragms are formulated in accordance to 21 CFR 177.2600 - Elastomers, and 21 CFR 177.1550 Perfluorocarbons
- Diaphragms are supplied with Certificate of Conformance per USP Class VI - Chapter 87 In-Vitro and Chapter 88 In- Vivo
- Diaphragms are available with Certificate of Conformance per ISO 10993-5, -6, -10 and -11
- Certificate of Compliance to EMEA/410/01 - BSE TSE Statement
- Certificate of Traceability to EN 10204 3.1 B available upon request.
- Diaphragm Direct® assures verified compliance with FDA, USP, ISO, and ASME BPE requirements through independent third-party testing.
- Diaphragm Direct® diaphragms are third-party seal tested per Standard EN 12266-1 Seal performance data available upon request.
- Diaphragm Direct® successfully tested per the 100/500 SIP Study for Diaphragm Valve Diaphragms ASME BPE Appendix J.1.2.1 - 60 Minute SIP Cycle (As tested in The BioProcess Institute's BioProcess Performance Reports®) (BPPR®). Copies of this comprehensive test data can be obtained directly from The BioProcess Institute.

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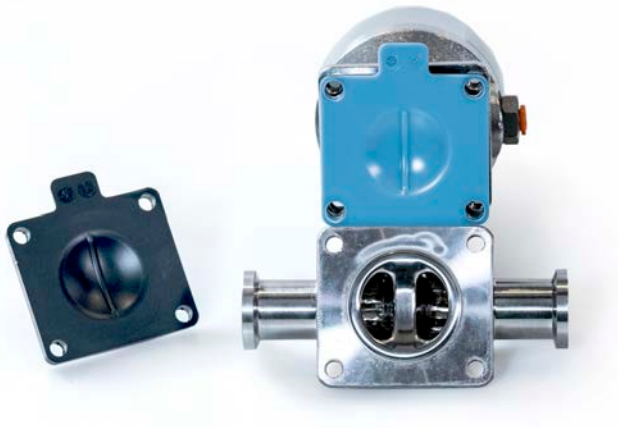
Diaphragm Direct®
Bio-Pharma Diaphragms

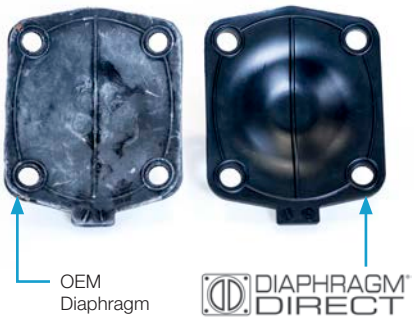
Diaphragm Construction

Replacement diaphragms for weir-style diaphragm valves, are dynamic seals and must be constructed to withstand the critical applications of the Biopharmaceutical industry. Every Diaphragm Direct® brand diaphragm incorporates fifty plus years of diaphragm manufacturing knowledge and experience.

DIAPHRAGM DESIGN

The diaphragm design must mirror the weir contour and the diaphragm body flange. Elastomer diaphragms must not be stretched to reach the valve's weir or allowed to fold, otherwise seal performance and service life will be impacted. The sealing bead across the center of weir, as well as any sealing bead around the circumference of the diaphragm face must also be mirrored. If the weir width of the diaphragm is too narrow, hot service can result in knife-like damage to the diaphragm, especially in PTFE type diaphragms.





Diaphragm Direct® employs the latest 3D CT/Laser scanning for reverse engineering into CAD models. Color error mapping software is used extensively during the diaphragm design process assuring that all Diaphragm Direct® diaphragms adhere to the design of the respective OEM. Utilizing 3D printing technology to generate diaphragm samples, diaphragm footprint, weir contour and sealing bead can be carefully reviewed and analyzed prior to the diaphragm mould fabrication.

DIAPHRAGM FABRICATION

Diaphragm Direct® elastomer diaphragms are produced by a compression molding process. The diaphragm is constructed with layers of polymer material and high performance woven fabric reinforcement for maximum strength and durability. PTFE diaphragm shields are produced by a compression and sintering process under cleanroom conditions. The diaphragm manufacturing process, quality, performance and reliability of all Diaphragm Direct® diaphragms is assured, third-party tested, and fully traceable.

Diaphragm Direct® uses a reinforcement fabric that is carried from end-to-end in the diaphragm and encompasses the diaphragm bolt circles. Designs that omit this internal reinforcement fabric depend upon the elastomer to bare all physical stresses and mechanical loads. Flex life is greatly reduced and the risk of premature diaphragm failure is increased.

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Diaphragm Direct®
Bio-Pharma Diaphragms

Seal Performance Testing

Diaphragms are dynamic gaskets and must be designed and manufactured to withstand the critical applications of the Biopharmaceutical industry. Diaphragm Direct® diaphragms are backed by 50+ years of diaphragm manufacturing experience and knowledge. Diaphragm Direct® diaphragms are designed, manufactured and tested to meet or exceed the pressure ratings and performance criteria of the OEM valve assembly.

EN 12266-1

- Per ASME BPE-2016's Section SG-4.3.1.1., Diaphragm Direct® diaphragms are third-party Seal Performance Tested according to EN 12266-1*. Both Diaphragm Direct® diaphragm type, (EPDM and TFM™ (PTFE) backed EPDM), undergo a Seat and Shell Bubble Test (Air and Hydraulic) per EN 12266-1. Seal Test Certificates are available upon request.
- Diaphragm Direct undergoes further seal performance testing per: ASME BPE-2016 Appendix J Standard Process Test Conditions for Seal Performance Evaluation.

EN 12266-1:2012

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12266-1

April 2012

ICS 23.060.01 — Supersedes EN 12266-1:2003

English Version

Industrial valves - Testing of metallic valves - Part 1: Pressure tests, test procedures and acceptance criteria - Mandatory requirements

Robinetterie industrielle - Essais des appareils de robinetterie métalliques - Partie 1: Essais sous pression, procédures d'essai et critères d'acceptation - Prescriptions obligatoires

Industriearmaturen - Prüfung von Armaturen aus Metall - Teil 1: Druckprüfungen, Prüfverfahren und Annahmekriterien - Verbindliche Anforderungen

This European Standard was approved by CEN on 25 February 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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SIP AND CIP PERFORMANCE TESTING

Diaphragm Direct® successfully completed the 100/500 SIP Study for Diaphragm Valve Diaphragms (ASME BPE Appendix J.1.2.1 - 60 Minute SIP Cycle" "As tested in The BioProcess Institute's BioProcess Performance Reports® (BPPR®). Diaphragm Direct diaphragms have undergone Chemical Effects static testing according to ASTM D471 Standard Test Method for Rubber Property - Effect of Liquids, as well as long-term static steam and static hot water testing.

Copies of The BioProcess Institute's BioProcess Performance Reports® (BPPR®) can be obtained directly from The BioProcess Institute (Tel: 401.294.9000) - info@bioprocessinstitute.com.

**EN 12266-1 International Equivalents: UNE EN12266-1:2013, NS EN12266-1:2012, NBN EN12266-1:2012, DIN EN 12266-1 (2012-06), UNI EN 12266-1:2012, NEN EN 12266-1:2012, NF EN 12266-1:2012, I.S. EN 12266-1:2012, ONORM EN 12266-1:2012, SS EN 12266-1 Ed. 2 (2012), NS EN 12266-1:2012, ONORM EN 12266-1:2012, UNE EN 12266-1:2013, UNE EN 12266-1:2003, SS EN 12266-1 Ed.2 (2012), NBN EN 12266-1:2012, UNI EN 12266-1:2012, NF EN 12266-1:2012, NEN EN 12266-1:2012*

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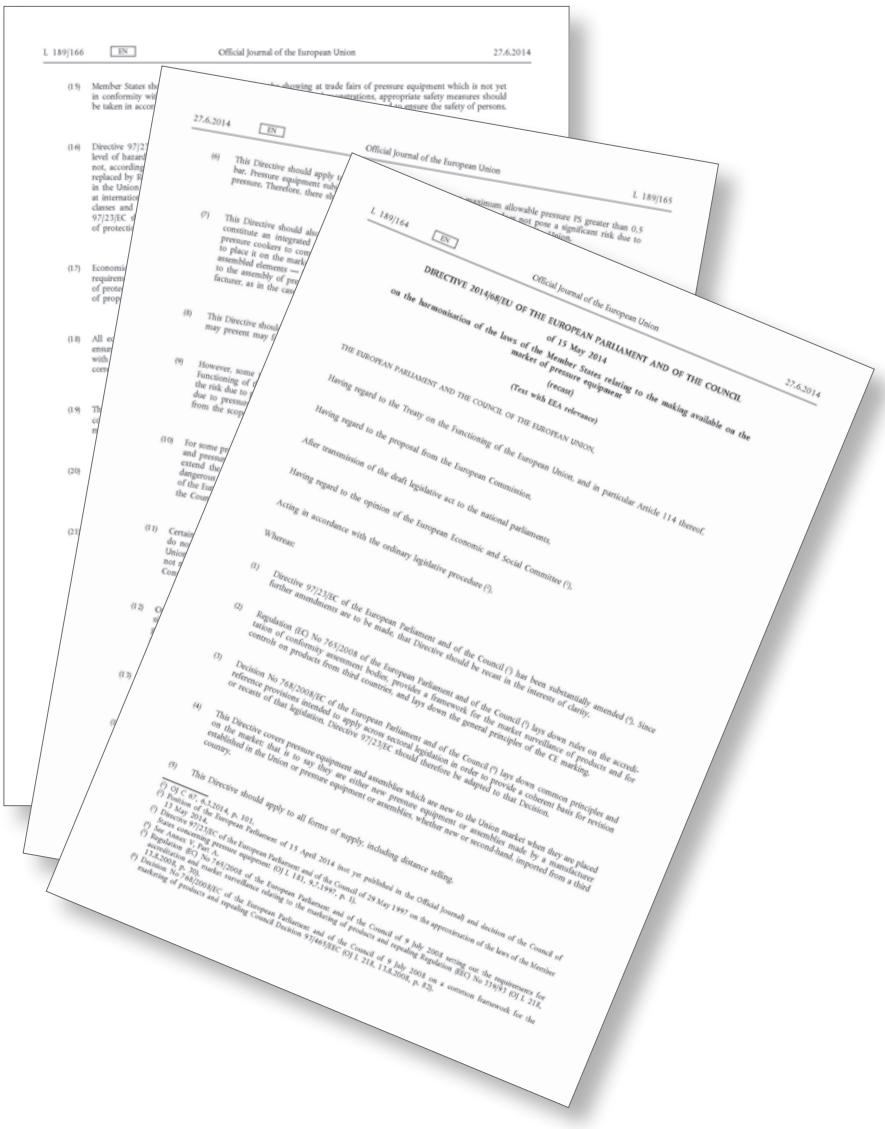
Diaphragm Direct®
Bio-Pharma Diaphragms

Seal Performance Testing

EUROPEAN PRESSURE EQUIPMENT DIRECTIVE 2014/68/EU

Pressure Equipment Directive 97/23/EC was replaced by a new Pressure Equipment Directive 2014/68/EU that is aligned to the EU's New Legislative Framework. Diaphragm Direct® diaphragms are in compliance to European Pressure Equipment Directive 2014/68/EU – Applied Harmonized Standard EN 12266-1**.

***As reviewed by TÜV SÜD America, Inc., Denver Colorado, USA.*


L 189/166 EN Official Journal of the European Union 27.6.2014

DIRECTIVE 2014/68/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast) (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

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Diaphragm Direct®
Bio-Pharma Diaphragms

Packaging

All Diaphragm Direct® diaphragms are packaged in individually sealed bags to prevent contamination and damage during transit, storage, and handling. The packaging has a clear side for viewing the enclosed diaphragm and a white backing with detail information pertaining to the enclosed diaphragm. The sealed package provides an extra level of assurance that the diaphragm has not been exposed to potential contamination during storage or maintenance activities prior to the diaphragm installation.

The Diaphragm Direct® packaged diaphragm provides the following information:

- a QR code that allows the end-user quick access to the Diaphragm Direct® website page for information on the packaged diaphragm. Compliance information and a line drawing on the diaphragm is available
- Diaphragm material of construction, and agency compliance
- Material Lot Number for full material traceability
- Diaphragm cure date and expiration date
- Country of Manufacturer
- Personnel responsible for packaging the diaphragm

Diaphragm Direct®
Bio-Pharma Diaphragms

Storage and Shelf Life

TEMPERATURE AND HUMIDITY
Diaphragms should be stored in a cool, dry location. Storage temperature should be below 77ºF (25ºC). Higher temperatures and condensation caused by humidity may cause certain forms of deterioration and shorten the service life of the diaphragms. Likewise, colder temperatures may cause the diaphragms to become stiffer and distortion may occur.

OXYGEN AND OZONE
Diaphragms should be stored in air-tight containers and protected from circulating air. Equipment capable of generating ozone such as mercury lamps, electric motors (AC or DC), and other equipment that produce electrical spark or discharge can be rather aggressive to elastomer products like diaphragms.

LIGHT
Diaphragms should be protected from direct sunlight and strong artificial light with ultra-violet content. Diaphragms should be kept in their original packaging until ready for usage. We suggest storing the diaphragms in dark or opaque containers.

DEFORMATION
Diaphragms should be stored in a relaxed condition – free from compression, tension or other deformation. Warping and distortion may occur if heavy objects are stored on top of the diaphragms.

CONTACT WITH METALS, LIQUID OR SEMI-SOLID MATERIALS
Copper, Iron, and Manganese can have a damaging effect on elastomer products like diaphragms. Care should be taken to protect the diaphragms – we recommend wrapping or separation with paper or polythene, otherwise, diaphragms should be kept in their original packaging until ready for usage. Diaphragms should not come into contact solvent oils, and greases while in storage as this will cause deterioration and shorten the service life of the diaphragms.

CLEANING
Do not use organic solvents such as carbon tetrachloride, trichloroethylene or petroleum spirit to clean the diaphragms. If the diaphragms require cleaning, we recommend mild soap and water.

ROTATION OF STOCK
The shelf life of diaphragms is dependent on many factors. Vulcanized rubber articles like diaphragms should remain in storage the least amount of time possible, and diaphragm stock should be rotated periodically. As a guide, the expected minimum storage life, if storage conditions are followed is as follows:

MINIMUM EXPECTED LIFE 10 YEARS
Elastomer Diaphragms – EPDM (Peroxide Cured, Post Cured), FPM, Buna, Dicumyl Cured Silicone

PTFE Diaphragms – PTFE(TFM™) backed EPDM, (Peroxide Cured, Post Cured), PTFE(TFM™) backed FPM, PTFE(TFM™) backed Dicumyl Cured Silicone

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