Diaphragms

Certification and Compliance for Validation

We recognise the importance of the validation process for products used in aseptic applications. We aim to provide the highest levels of reliability and regulatory compliance through the complete supply chain to provide a complete package of documentation for all components in contact with the process fluid. For the diaphragm, a key component in any diaphragm valve this means;

- All resins and additives used in the manufacturing process are FDA compliant.
- Compounding, physical properties and manufacturing processes are documented
- All diaphragms have a certificate stating conformance to FDA requirements
- Elastomers comply with 21CFR177.2600
- Perfluorocarbon resins comply with 21CFR177.1550
- Certificate of conformance available to USP 28 Class VI, Chapter 87 In-Vitro and Chapter 88 In-Vivo
- Testing performed for extractable organic substances in accordance with ISO 10993-18 (detection by GC-MS)
- Certificate of conformance to 3-A
- Certificate of compliance to EMEA/410/01 “Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medical Products”
- Certificate of traceability according EN 10204 3.1 of compounding and moulding process with material analysis
- Diaphragm traceability data available upon request
- Test data available upon request

Diaphragm Traceability

All diaphragms are clearly identified and are batch traceable by a set of unique codes moulded into the diaphragm during the manufacturing process. The traceability includes the material formulation and mechanical and physical properties. The picture shows the permanent markings on the diaphragm. Depending on the size and material of the diaphragm, the location of the markings may vary.

Diaphragm information is provided on the order and shipping documents as well as on the packaging. The actual information provided is shown below. The information show in bold type is available when a Material Analysis Traceability Certificate DIN EN 10204 3.1 for manufacturing and formulation is requested.

On the order and shipping documents:
- Article number, material code with description
  - Customer article number
  - Batch number
  - Shelf Life

On packaging in which the diaphragm is bagged and sealed:
- Article number, material code with description
- Internal order series number
- Packaging quantity
- Customer article number
- Batch number
- Shelf Life
Diaphragms

The diaphragm is the most important component of the diaphragm valve. Besides the valve body, the diaphragm is the only part of the valve which contacts the process medium. It plays a vitally important role in isolating the process medium from the actuator or top works and the external atmosphere, as well as being the dynamic element of the valve, controlling and stopping the process medium. The development and formulation of diaphragm compounds is performed in conjunction with a specialist company. This relationship has been in place for many years. Our diaphragms are subject to our very stringent testing as well as by third party organisations. These tests are performed continuously using different process fluids and diaphragm compounds. They are designed to simulate as close as possible real processes.

One of the tests is performed in an automatic saturated steam sterilisation loop. (see picture below). The tests result have an influence on the diaphragm design, the composition of the materials, the valve body design, the actuation and the design of the complete valve assembly. All diaphragms, except the smallest are produced with an embedded stainless steel compressor stud to engage the diaphragm with the valve operating mechanism. The smallest diaphragm uses an elastomer button. All diaphragm of the same size, regardless of composition have the same engagement with the valve operating mechanism and may be interchanged in the valve without changing the diaphragm compressor and spindle.

Diaphragm Dimensions MA 25 - 80

<table>
<thead>
<tr>
<th><strong>MA</strong>*</th>
<th>25</th>
<th>40</th>
<th>50</th>
<th>80</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>46</td>
<td>65</td>
<td>78</td>
<td>114</td>
</tr>
<tr>
<td>B</td>
<td>54</td>
<td>70</td>
<td>82</td>
<td>127</td>
</tr>
</tbody>
</table>

*Diaphragm size
Diaphragms

EPDM
EPDM is a specifically developed elastomer compound reinforced with a vulcanised woven fabric inlay. It is always manufactured in the moulded open position. This diaphragm construction achieves higher stability for the diaphragm at elevated temperatures and pressures. In addition, the woven fabric inlay is vulcanised over the embedded compressor stud in order to strengthen the elastomer-metal connection, this makes it ideal for vacuum applications.

PTFE (TFM)
These PTFE diaphragms have been designed to offer the highest degree of chemical resistance, increased stability, longer flex life, less porosity, reduced cold flow and superior performance through temperature fluctuations between hot and cold and steam sterilisation cycles.

MA8 and MA10
The diaphragm dimensions MA8 and MA10 are designed as one-piece diaphragms: This means that the EPDM back is bonded with the PTFE. The diaphragm is always manufactured in the moulded open position. These one-piece diaphragms have less surface area and are subject to shorter linear strokes which explain the excellent performance that has proved itself over time.

MA8 diaphragms incorporate an elastomer button for assembly with the valve operating mechanism. The MA10 uses a threaded stud assembly. Both these features eliminate the potential for point loading at the centre of the diaphragm.

MA25 to MA100
The diaphragm dimensions MA25 to MA100 are designed as two-piece diaphragms-consisting of a separate EPDM backing cushion and PTFE diaphragm. The diaphragm is always manufactured in the moulded closed position. The advantage of this design for the MA25 to MA100 is that this reduces the force to close the valve and increases the life of the diaphragm. In the two piece diaphragms the threaded stud connection is embedded in the PTFE of the diaphragm. To eliminate the potential of point loading at the centre of the diaphragm, a floating suspension connection to the valve operating mechanism is used.

<table>
<thead>
<tr>
<th>Material</th>
<th>MA 8 - 100</th>
<th>8, 10, 25, 40, 50</th>
<th>25 - 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>One-piece</td>
<td>One-piece</td>
<td>Two-piece</td>
</tr>
<tr>
<td></td>
<td>Moulded open</td>
<td>Moulded open</td>
<td>Moulded closed</td>
</tr>
<tr>
<td>Temperature range (°C)</td>
<td>-40 to +150</td>
<td>-20 to +150</td>
<td>-20 to +160</td>
</tr>
</tbody>
</table>

The listed temperatures may apply to clean steam sterilisation protocols and may not apply to continuous steam service. Upon request, other diaphragms are available with other materials, bigger sizes and for higher temperature up to 175°C.