

GEMÜ Code 54

PTFE/EPDM diaphragm

EN

Operating instructions

General Information Document



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1 Background

As part of 3M's withdrawal from fluoropolymer production, replacement raw materials have been qualified for the manufacture of one-piece code 54. laminated PTFE diaphragms. No new code is being introduced. The one-piece laminated diaphragms will continue to be available under code 54.

2 Details of the change

1. The PTFE foil material that comes into contact with the process media is replaced with an alternative PTFE from renowned manufacturers.
2. The designs and dimensions will remain unchanged.
3. The diaphragm backing (which does not come into contact with the product) will remain unchanged.

3 Regulatory requirements

As part of an equivalency test, the code 54 PTFE diaphragms have been tested with regard to their performance capability and properties. As the minimum requirement for equivalency has been met within the endurance tests and those of the approval process with the alternative materials have been successfully passed through again, all of the existing approvals and conformities will remain unchanged. As a result, the diaphragms continue to meet all of the relevant regulatory requirements and can be used in the previous areas of application without any restrictions.

4 Advantages

In the changeover of the material and in addition to all previous approvals/conformities, food conformity in accordance with the Japanese Food Contact Material Act and for China (GB4806.6/GB4806.7/GB4806.11/GB9685) has been applied and accredited. This means that they are now also available for the new alternative materials.

5 Endurance tests

The operating time of code 54 diaphragms has been tested using endurance tests and compared with the previous laminated PTFE diaphragms. The code 54 test diaphragms with the alternative materials are assembled on valves by trained personnel. Leak testing in accordance with DIN EN 12266 is carried out before, after and during endurance tests. These tests are used to determine whether, and to what extent, the leak-tightness characteristics of the diaphragms are reduced by the stresses of the endurance tests. The endurance tests result in artificial ageing due to the effects of mechanical and thermal stress as well as direct contact with corrosive media. Once the test valve has completed the specified test programme, it is removed and a final leak test is carried out. Following this, the test valve is disassembled and the diaphragm is analyzed for faults by diaphragm experts.

The sterility endurance test is run in cycles. During a sterility cycle, the test valve is exposed to steam, vacuum and cold water. From our analysis of the results of our testing, GEMÜ can state the code 54 diaphragm made from PTFE alternative materials has equal or better performance than the previous diaphragms that it is replacing.

The following tests were performed:

1. Sterility test (as described above)
2. Steam endurance test
3. Leak-tightness testing (before, after and during endurance tests)
4. Determining the pin pull-out forces
5. Determining the maximum pin torque

6 Batch testing

Every new diaphragm batch is tested by GEMÜ's quality assurance department. The diaphragm surface, dimensional tolerances and hardness are checked by quality assurance staff. For every diaphragm batch, a steam endurance test with leak measurement according to DIN EN 12266 is carried out. Diaphragm batches are only released for use if they pass all quality tests within the tolerance values.



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Subject to alteration

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