

USP Class VI Certified Diaphragms for Biopharmaceutical Applications

HC4 Diaphragm Valves

HC4/025/01/09.03

To meet the stringent quality assurance demands of the biotechnology and pharmaceutical process industries a range of elastomer and PTFE diaphragms are available certified to USP Class VI.

The USP standard defines a series of tests to determine the biological response to elastomers and plastics used in medical implants or other devices.

All of the certified diaphragms meet the criteria in Section <88> Biological Reactivity Tests, In Vivo Plastic Classes 1 to V1 -186°F (-121°C).

Testing was undertaken by the independent accredited laboratory Huntingdon Life Sciences (UK).

Each diaphragm is available with a certificate confirming USP Class VI conformance.

Approved Diaphragm Grades

- 300 grade Isobutylene isoprene.
- 425 grade Ethylene Propylene peroxide cured co-polymer
- E3 EPM grade Ethylene Propylene co-polymer, post cured for 144 hours at 240°F (127°C).
- 214/300 grade PTFE/Isobutylene isoprene.
- 214S/300 grade TFM/Isobutylene isoprene.
- 214/425 grade PTFE/Ethylene Propylene co-polymer.
- 214S/425 grade TFM/Ethylene Propylene co-polymer.

Additional Approvals

Elastomer diaphragms conform to para 177.2600, of Section 21 code of Federal Regulations revised 1st April 2003.

PTFE diaphragms conform to para 177.1550, of Section 21 code of Federal Regulations revised 1st April 2003.

Manufacturing Traceability to EN 10204 3.1b

Size Availability

Elastomer diaphragms 0.25"-8.00"(DN8-200)

214 (PTFE) 0.25" to 8.00" (DN8-200)

214S (TFM) 0.25" to 8.00" (DN8-200)

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