

## CERTIFICATE OF COMPLIANCE

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**Crane Saunders Material Grade: 425**

**Polymer: Ethylene Propylene Monomer (EPM)**

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**Catalogue Code: E2**

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Pharmacopoeia:

USP Class I to Class VI

This Polymer has been tested and certified in accordance with U.S Pharmacopoeia Class VI, Sections <87> and <88> Biological Reactivity Tests, In-Vivo and In-Vitro. The product fully complies with Biological Reactivity Tests, in Vivo, Plastic Classes 1 to V1 – 121°C.

The tests include:

1. Cytotoxicity
2. Acute systemic Toxicity
3. Intracutaneous test
4. Intramuscular

USP381

This Polymer has been tested and certified in accordance with U.S. Pharmacopoeia 381 (USP381) Elastomeric enclosures for Injections.

The equivalent tests in Europe include compliance to European Pharmacopoeia (EP) 3.2.9.

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FDA

Diaphragms manufactured from this Polymer comply with materials listed in the relevant sections of the American Food and Drugs Administration Code of Federal Regulations, Chapter 1, Title 21, Part 177, para 2600 *"Rubber Articles Intended for Repeated Use"*

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EC1935/2004

Diaphragms manufactured using this grade of Polymer have been tested to and comply with the EC Directive 1935/2004. The standard in line with this requirement is BS EN 12868:1999.

Good Manufacturing Practice (GMP)

In line with EC1935/2004, this product has been manufactured using GMP to EC 2023/2006

REACH

Diaphragms manufactured using this Polymer comply with EU 1907/2006 regulations

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**ADCF**

Diaphragms manufactured using this grade of Polymer utilise ingredients that are of an Animal Derived Compound Free [ADCF] origin. This includes bovine and Transmissible Spongiform Encephalopathies (BSE and TSE).

This material complies with European legislation EC 999/2001

For and on behalf of  
Crane Process Flow Technologies  
Technologies

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Crane Process Flow



**Pete Gill**  
**Engineering Manager**  
**Manager Saunders**



**Andrew Powell**  
**Vice President/General**