

FDA Diaphragm Conformance

HC4 Diaphragm Valves

Diaphragm Options

There are three main categories of diaphragm that comply with FDA regulations.

- Synthetic rubber, black reinforced Grade numbers 300, 425 and E3.
- Synthetic rubber, white reinforced E4.
- PTFE, virgin grade, white. 214, 214S with 300 or 425 support backing.

Type A/AFP diaphragms are manufactured in the size range 0.25"-8" (DN8 to DN200) for application with the HC4 range of diaphragm valves and are available with a Certificate of Conformity (see below) to FDA Code of Federal Regulations, Chapter 1, Title 21, Part 177, para 2600 Rubber Articles Intended for Repeated Use and para 1550 Perfluorocarbon resins, Issue Revised April 1st 2003.

In accordance with Sub-section (e) of para 2600 the certificate will also detail the level

of extractables, the test carried out by an independent laboratory, which simulates contact with aqueous food.

Further information regarding the qualitative identification will be available upon written request under supplier/customer confidentiality agreement.




Diaphragm Specification

- 300 Butyl (IIR) Isobutylene Isoprene, Black Reinforced, resin cured.
- 425 Ethylene Propylene co-polymer, peroxide-cured.
- E3 Ethylene Propylene co-polymer, post cured for 144 hours @ 240°F (127°C).
- 214 Standard Virgin PTFE.
- 214S TFM with high Creep Resistance where intermittent steam is used.
- E4 EPDM, White, Sulfur Cured.

Before Use

- Check correct grade for process.
- Check diaphragm for damage from handling and transit.
- If the diaphragms are washed or sterilized, dry before fitting.
- Use recommended bolting torques for installation, see spares pack fitting instructions.
- Where steam is used check maximum temperate performance of diaphragm against steam pressure and temperature.
- On vacuum application use Suffix V grade on rubber grades 3" (DN80) and above or TFM 214S all sizes.

HC4/020/01/09.03

 Process Flow Technologies <small>A Crane Co. Company</small>	
<p><i>Certificate of FDA Conformity</i></p> <p>Saunders Grade 214S425 Diaphragms</p>	
<p>This is to certify that the Saunders grade 214S425 diaphragms are manufactured from materials listed in the relevant sections of the FDA Code of Federal Regulations, Chapter 1, Title 21, Part 177, para 2600 Rubber Articles Intended for Repeated Use and para 1550 Perfluorocarbon resins, Issue Revised April 1st 2002</p>	
<p>The Saunders grade 214S425 diaphragms are manufactured from a modified PTFE facing and organic peroxide cured Black EPM co-polymer [Ethylene Propylene Monomer] compound, formulated by Saunders' own technologists, to comply with the current Food and Drug Administration Regulations.</p>	
<p>Furthermore, the Saunders grade 214S425 PTFE/EPM diaphragms have undergone intensive product testing for aqueous and fatty food contact, confirming the suitability of the PTFE compound, with regard to extractables, as laid down in the American Food and Drug Administration Regulations, Sub-section (e) of para 2600.</p>	
<p>For and on behalf of Crane Process Flow Technologies</p>  <p>D. Preston Quality Manager</p>	<p>For and on behalf of Crane Process Flow Technologies</p>  <p>Dave Birch, B.A. [Hons] Biopharm Product Manager</p>
<p><small>Crane Process Flow Technologies Ltd. Grange Road, Cwmbran, Gwent, UK NP44 3XX Telephone: +44 (0) 1633 486666 Fax: +44 (0) 1633 486777 www.saundersvalves.com www.craneflow.com Registered in England Number: 447239</small></p>	

CRANE 

FDA Conformance

The diaphragm grades that comply with FDA are manufactured in accordance with the regulation (para 2600) which defines the polymer and compounding ingredients that can be used. There are limitations on the amount of certain compounding ingredients.

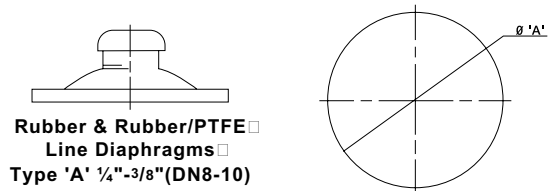
- Accelerators, total not to exceed 1.5% by weight of rubber.
- Retarders, total not to exceed 10% by weight of rubber.
- Activators, total not to exceed 5% by weight of rubber, except magnesium oxide which is permitted at higher levels.
- Antioxidants/Antiozonants, total not to exceed 5% by weight of rubber.
- Plasticizers, total not to exceed 30% by weight of rubber.
- Fillers, no maximum given except for carbon black.
- Carbon black, channel process or furnace combustion process, total not to exceed 50% by weight of rubber, furnace combustion black content not to exceed 10% by weight of rubber product intended for use in contact with milk or edible oils.
- Colors, total not to exceed 10% by weight of rubber.
- Lubricants, total not to exceed 2% by weight of rubber.
- Emulsifiers, no maximum given.
- Sulfur, no maximum given.

Extractables

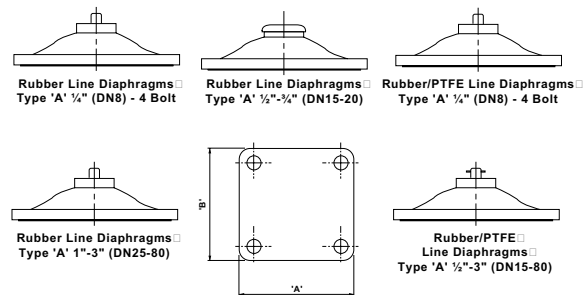
Sub-section (e) of paragraph 2600 stipulates the procedure for the evaluation of the finished rubber product for contact with aqueous foods. The food contact surface is extracted with distilled water at reflux temperature and shall yield in total not more than 20 milligrams per square inch during the first 7 hours of extraction, and not to exceed 1 milligram per square inch after the succeeding 2 hours of extraction.

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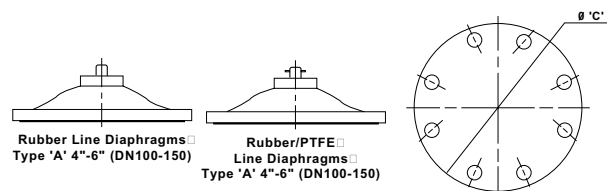
Diaphragm Dimensions



Size (DN)	A (mm)
0.25" (8)	1.10" (28)
0.38" (10)	1.42" (36)



Size (DN)	A (mm)	B (mm)
0.25" (8)	1.38" (35)	1.30" (33)
0.50" (15)	1.89" (48)	1.73" (44)
0.75" (20)	2.44" (62)	2.24" (57)
1.00" (25)	2.80" (71)	2.64" (67)
1.50" (40)	3.94" (100)	3.54" (90)
2.00" (50)	4.92" (125)	4.17" (106)
2.50" (65)	5.67" (144)	5.20" (132)
3.00" (80)	7.44" (189)	6.89" (175)



Size (DN)	C (mm)
4.00" (100)	8.86" (225)
5.00" (125)	10.00" (254)
6.00" (150)	12.01" (305)