



Fusion™ SD716
(FKM)
Statement of Compliance

Fusion™ SD716 meets the extractive limitations prescribed in the Food and Drug Administration, 21 C.F.R. Section 177.2600, “Rubber Articles Intended for Repeated Use”.¹

Fusion™ SD716 has been tested in accordance with United States Pharmacopeia (USP) Standards for use in pharmaceutical applications. More specifically, **Fusion™ SD716** has been evaluated under USP <87> (“Biological Reactivity Tests, *In Vitro*”) and USP <88> (“Biological Reactivity Tests, *In Vivo*”) and meets applicable requirements for Class VI polymers.²

Fusion™ SD716 has been evaluated according to the test procedures contained in the 3-A sanitary standards for multiple-use rubber and rubber-like materials used as product contact surfaces in dairy equipment, number 18-03. The material is covered by the scope and applicable definitions in these standards. The material complies with the applicable material and compatibility criteria found in sections C and D for a Rubber Class I material.³

Medical Use

CAUTION: Fusion™ fluorocarbon elastomers are not intended for use in medical applications involving implantation in the human body. For all medical applications, consult the Greene, Tweed & Co. Life Sciences Department.

Fusion™ is a trademark of Greene, Tweed & Co.

¹ Extraction tests in accordance with 21 C.F.R. Section 177.2600 were conducted by NAMSA, an independent testing laboratory. Results available upon request. (CER 20870, 20514 & 22809)

² Testing requirements in accordance with USP <87> and <88> (Class VI) were conducted by NAMSA. Results available upon request. Testing of finished articles that incorporates Fusion™ SD716 fluorocarbon elastomer under USP Standards is the responsibility of the manufacturer or seller of the finished article. (CER 20870, 20514 & 22809)

³ Testing requirements in accordance with 3-A sanitary standards for multiple-use rubber and rubber-like materials used as product contact surfaces in dairy equipment, number 18-03 were conducted by ARDL. (CER 21841) Results available upon request.