



1684 South Broad Street, PO Box 1307
Lansdale, PA 19446

Fluoraz® SD890 (FEPM) Statement of Compliance

Fluoraz® SD890 is permitted for use in the fabrication of molded parts (including a-rings, gaskets, diaphragms and other materials that function primarily as components of sealing applications) for food processing equipment in accordance with the United States Food and Drug Administration (FDA) **Food Contact Notification (FCN) 246**.¹

In accordance with the requirements set forth under FCN 246, **Fluoraz® SD890** also meets the extractive limitations prescribed in 21 C.F.R. Section 177.2400 ("Perfluorocarbon cured elastomers"), paragraph (d).²

Fluoraz® SD890 has been tested in accordance with United States Pharmacopeia (USP) Standards for use in pharmaceutical applications. More specifically, **Fluoraz® SD890** 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.³

Fluoraz® SD890 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.⁴

Medical Use

CAUTION: Chemraz® perfluoroelastomers are not intended for use in medical applications involving implantation in the human body. For all medical applications, consult Greene, Tweed & Co., LLC Material Compliance.

Name: Shawn McCloskey

Title: Chief Commercial Officer

Signature:

DocuSigned by:

C776757875104E7...

Date: August 04, 2026

Fluoraz® is a registered trademark of Greene Tweed.

1. [FCN No. 246](#) (effective August 13, 2002).
2. Extraction tests in accordance with 21 C.F.R. Section 177.2400 were conducted by NAMSA, an independent testing laboratory. Results available upon request. (CER 20870, 20514 & 22809)
3. 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 Fluoraz® SD890 perfluoroelastomer under USP Standards is the responsibility of the manufacturer or seller of the finished article.
4. 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.
5. This information is reviewed and checked for accuracy and updated on an annual basis.