



## Fluoraz<sup>®</sup> SD890 (FEPM)

### Statement of Compliance

**Fluoraz<sup>®</sup> SD890** is permitted for use in the fabrication of molded parts (including o-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**.<sup>1</sup>

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

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

**Fluoraz<sup>®</sup> 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. <sup>4</sup>

#### Medical Use

CAUTION: Fluoraz<sup>®</sup> 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.

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Fluoraz<sup>®</sup> is a registered trademark of Greene, Tweed & Co.

<sup>1</sup> See <https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=246> (effective August 13, 2002).

<sup>2</sup> 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)

<sup>3</sup> 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<sup>®</sup> SD890 fluorocarbon elastomer under USP Standards is the responsibility of the manufacturer or seller of the finished article. (CER 20870, 20514 & 22809)

<sup>4</sup> 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.