Chemraz® SD585

(FFKM)
Statement of Compliance

Chemraz® SD585 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) 247.[1]

In accordance with the requirements set forth under FCN 247, **Chemraz® SD585** also meets the extractive limitations prescribed in 21 C.F.R. Section 177.2400 ("Perfluorocarbon cured elastomers"), paragraph (d).[2]

Chemraz® SD585 has been tested in accordance with United States Pharmacopeia (USP) Standards for use in pharmaceutical applications. More specifically, **Chemraz® SD585** 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]

Chemraz® SD585 complies to EC1935-2004 per national requirement BfR XXI, category 4 for seals and similar commodity parts.

Medical Use
CAUTION: Chemraz® perfluoroelastomers 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.

Chemraz® is a registered trademark of Greene, Tweed & Co.

1 *See* https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=247 (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 Chemraz® SD585 perfluoroelastomer under USP Standards is the responsibility of the manufacturer or seller of the finished article.