



Certificate of U.S.P Class VI Compliance

Kaltraz Diaphragm

Advant O Seal, certifies that the **Kaltraz** fluoroelastomer material utilized to manufacture the **Kaltraz** Diaphragms has been tested and certified in accordance with the United States Pharmacopoeia Class VI by an accredited third party Biological Test Center.

The **Kaltraz** fluoroelastomer fully complies with the Biological Reactivity Test as follows:

Intracutaneous Test

Systemic Injection Test

Implantation Test

Tests comply with USP Class VI revision 05/2013.

The peroxide cured **Kaltraz** fluoroelastomer passes Cytotoxicity testing and meets FDA 21 CFR 177 2600

Description: 1.0" Diaphragm

Cured Date: 4 - Q - 2013

Authorized representative: Pete Marcilese

Signed: **Pete Marcilese**

Date: 12/12/13