



SaniSure®

Be sure.

## CERTIFICATE OF CONFORMANCE

Manufacture Date: SAMPLE

Client: SAMPLE

Order Number: SAMPLE

Customer P/N: SAMPLE

Assembly PartNumber: SS-SB-1051-PVDF-G


Lot # SAMPLE

Lot Quantity:

SaniSure, Inc. hereby certifies the products have been manufactured with materials meeting the following criteria:

- Contains only materials approved under FDA regulations 21CFR 177.1520 and 21CFR 177.2600, USP Class VI, USDA, 3A for contact with food and drugs,
- Assembled and packaged within ISO 7 cleanroom environment,
- Sterilization: Sterilized by gamma irradiation at 27.5 - 45 kGy,
- Gamma-Irradiation Validation has been performed assuring SAL  $10^{-6}$  per ANSI/AAMI/ISO11137-2 ( $VD_{max} 27.5$ )

SIGNED: \_\_\_\_\_

  
Kent Jeronimus, Quality Control

**THIS MATERIAL IS NOT INTENDED FOR IMPLANTATION**

Customers must make their own determination that their use of the above product(s) is safe, lawful and technically suitable for their intended use. For questions on intended use of this product, please contact:

SaniSure, Inc.  
1020 Flynn Rd, Camarillo CA 93012  
(877) 777-3005 [www.SaniSure.com](http://www.SaniSure.com)