



DECLARATION OF FOOD CONTACT COMPLIANCE

Issue Date: Oct 7, 2013

Issued on behalf of and by:

W. L. Gore & Associates, Inc.
Gore PharmBIO Products
402 Vieve's Way
Elkton, Maryland 21921, USA

This declaration of compliance applies to the following product(s):

GORE® STA-PURE™ Style 1200 Sheet Gasketing

GORE® STA-PURE™ Style 1500 Pipe Gaskets

Product Manufacturer

This product is manufactured by Gore PharmBIO Products, a business unit of W.L. Gore & Associates, Inc.

Quality System

Gore PharmBIO Products adheres to relevant cGMP practices and the quality system is certified to ISO9001.

Product Application

It is the responsibility of the customer to determine the suitability of the GORE® STA-PURE™ Style 1200 Sheet Gasketing and GORE® STA-PURE™ Style 1500 Pipe Gaskets for the customer's particular application.



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Declaration of Compliance to Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food:

GORE® STA-PURE™ Style 1200 Sheet Gasketing and GORE® STA-PURE™ Style 1500 Pipe Gaskets are intended for repeated use in the production of all types of food at all temperatures as it complies with the regulatory and legislative requirements of (EC) No 1935/2004 and the following:

- (1) (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food;
- (2) (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

Declaration of Compliance to U.S. Food and Drug Administration, Code of Federal Regulations, Title 21

This GORE® STA-PURE™ Style 1200 Sheet Gasketing and GORE® STA-PURE™ Style 1500 Pipe Gaskets may be used for repeated contact with all food types and under all conditions of use as it complies with relevant FDA requirements regarding food contact substances.

Consistent with 21 CFR 174.5(d), each component is composed of substances that are either:

- (1) listed or affirmed as generally recognized as safe under 21 CFR Parts 182 or 184;
- (2) covered by, and meeting all relevant specifications and other requirements in an indirect food additive regulation under 21 CFR Parts 175, 176, 177 and 178; or
- (3) used in accordance with an effective food contact substance notification under section 409(h) of the FFDCA.

Certified by: Jacques Rene, Jr.



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About Gore PharmBIO Products

Our technologies, capabilities and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers.

All products in the Gore PharmBIO portfolio are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

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All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Specifications are subject to change without notice. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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