

Catalog Number: 22150240

Lot Number: D02A3251

Description: Fisherbrand™ DuoClick Specimen Containers

CERTIFICATE OF COMPLIANCE AND STERILITY

Quality System Compliance:

Products are manufactured under FDA and ISO guidelines. Products are inspected and controlled through the entire production processing in accordance with the current applicable product specifications and quality inspections procedures. Inspection records are reviewed and signed off by qualified personnel for product release.

Product Specification:

The below listed products are Class I category device as defined by the FDA in 21CFR Parts 862-892.

Sterilization Process:

The Sterile products, when applicable, as listed below have been processed for sterility by irradiation method in order to achieve a minimum Sterility Assurance Level (SAL) of 10⁻³, in accordance with the following guidelines and standards:

- 21 CFR Part 820 US FDA GMP — Quality System Regulations (June 1997)
- ISO 13485:2003 Quality management System for Medical Devices
- ISO 11137:2006 Sterilization of Healthcare Products

Material:

Latex Free: The resins used to manufacture the below products are from prime virgin medical grade materials, which meet the FDA requirements of 21CFR 177.1520. Such resins do not contain latex, BPA, DEHP and any other Phthalates. Thus, they are recommended for use in food, beverage and medical applications.

BSE/TSE: The goods manufactured by our supplier do not contain products from animal origin. These products do not contain, make use of, or involve, at any point of their respective manufacturing process, raw materials of animal origin (including animal proteins). Our supplier does not store products of animal origin (including animal proteins) in its manufacturing and warehouse facilities.

This Certificate has been compiled with data that has been provided by the manufacturer of the product. The Fisher Scientific channel has not independently verified such data. This document has been produced electronically and is valid without a signature.

DNase/RNase: Using prime virgin FDA compliant resin, without use of any mold release or additive through the molding process, should allow the below products to be free of DNase/RNase contaminants.

Pyrogenicity: The above products have been manufactured under very low bioburden conditions and as a result, the inner surface of these products should remain free of pyrogenic contaminant.

Responsibility and Awareness:

It is the responsibility of the customer to determine that above listed products as manufactured by our supplier or products/articles produced from the above are acceptable and suitable for use in the customer intended applications.