Certificate of Quality

VWR® SPECIMEN CONTAINERS WITH DUAL CLICK

As per the manufacturer, the below product meets the following criteria:

VWR Catalog Number	10803-990
Manufacturing Lot Number	J17A3191
Description	VWR SPECCONT 120/53 STERL GRN DUALCLICK
Sterilization Lot Number	G1019191
Country of Origin	United States of America
Shelf Life	Not Applicable

Quality System Compliance

The manufacturing facility is registered with Food and Drug Administration (FDA). 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 Specifications

The product is Class I category device as defined by the FDA in 21CFR Parts 862-892.

Material: Latex Free. The resins used to manufacture the product is 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.

Sterilization Process: The product has 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:

-Tile 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

BSE/TSE Statement: The products manufactured 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). The manufacturer does not store products of animal origin (including Animal proteins) in their manufacturing and warehouse facilities.

Pyrogenicity: The product has been manufactured under very low bio-burden conditions and as a result, the inner surface of the product should remain free of progenic contaminant.

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

Responsibility and Awareness: *It is the responsibility of the customer to determine that above product or products/articles produced from the above are acceptable and suitable for use in the customer intended applications.*

Signed:

Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: **January 03, 2020**