



March 25, 2021

## CERTIFICATE OF ANALYSIS

Part No: C15217  
Lot No.: 645551  
Date of Mfr: 02/04/2021  
Description: LINER, SET OF 6 - STERILE

### **Product Conformance:**

P/N(s) **C15217**— The product described has been manufactured, inspected and tested in accordance with FDA 21 CFR Part 820(CGMP), ISO 13485 & meets or exceeds the requirements of the drawing noted.

**C15217** Liners which contains: **369255** – liner, JLA-8.1/9.1K, which is made of a polyurethane material that complies with the U.S. Pharmacopeia criteria for a Class VI plastics.

### **Animal Origin Statement:**

We confirm the raw material used in this product does not contain any animal derived materials in the manufacture or formulation of this product.

Additionally, during processing and manufacturing process, the product does not come in contact or is exposed to any other form of animal derived materials.

Be aware that Beckman Coulter does not test for the presence of these substances and that this statement is based upon documentation from our raw material suppliers.

### **Product Sterility:**

When applicable, the validated sterilization process certifies product labeled as sterile to have a sterility assurance level of 10<sup>-6</sup>. Product sterility is assured for 3 years from the date of manufacture if package is unopened, undamaged, and stored dry at temperatures between 15° to 25°C (59°-77°F).

A handwritten signature in black ink, appearing to read 'William Swanson'.

William Swanson  
Senior Quality Assurance Engineer