

ISO EN 13485:2012

# Certificate of Compliance

Catalog Number:

PCR-96-LP-FLT-W

Lot Number:

19014259

Product Description:

96 Well White Low Profile Flat Top PCR Microplate

Shelf Life : 3 years

### Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits – Year of manufacture; Last 3 digits - Batch identification

## Material:

Polypropylene

### Endotoxin (pyrogen) Testing:

This product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72 *Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing.* The acceptance level for product is less than 0.05 EU/mI.

#### **RNase/DNase Testing:**

This product has been tested according to our internal protocol and is free of any detectable RNase/DNase contamination and is confirmed by a gel assay.

#### Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure: Visual Attributes

Functional

Leak Test

Dimensional

**Results:** Pass Pass Pass Pass

Kelly C. McMullin Quality Manager

Rev No: 1