

## Certificate of Quality

Affix Product  
Label Here

This is to certify that the product as indicated by the affixed label complies with the following descriptions and specifications:

### Product Description – ProConnex® Tube set

All materials of construction are 100% lot traceable.

**Testing:** Lots for part numbers ending in T and V have been integrity test at AQL level 4.0. Part numbers ending in U and W have been 100% integrity tested.

**Shelf-life:** Intended for single-use within three (3) years from the date of manufacture for irradiated products and five (5) for non-irradiated products.

**Storage:** Store in original packaging at ambient conditions protected from moisture, extreme temperatures, and light.

Part numbers ending in I, S, T or U have been exposed to 25-40kGy of gamma radiation after final packaging. These parts are certified as sterile in accordance with the VDmax method, ANSI/AAMI/ISO 11137-1 AND 11137-2. This is not applicable to part numbers ending in N, V or W.

Manufactured in the United States of America.

All materials in product fluid path meet USP Class VI requirements and are compliant with EMA/410/01 guidelines (TSE/BSE/Animal Derived Component Free).

Repligen is an ISO 9001 certified company and products are manufactured meeting Repligen's quality management system.

This product was assembled in an ISO Class 7 cleanroom

### Issued by Quality Assurance

Electronically produced and valid without a signature

Please note that it is incumbent upon the end user to validate that this product is suitable for the intended use in their application.