

Certificate of Quality



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|---------------------|---------------------------------------------------------|
| Part Number | 2AT-616-TC-10 |
| Part Revision | 04 |
| Lot Number | EFRM408292 |
| Part Description | SterilEnz®-II/AT Fitting - Polypropylene 3/8" x 1.5" TC |
| Date of Manufacture | 09/2020 |
| Expiration Date | 08/2025 |
| Country of Origin | USA |

Quality System Compliance

- This product was manufactured in an ISO 9001 and ISO 13485 certified, FDA cGMP-compliant facility.
- This product was manufactured and packaged in a certified ISO Class 7 (10,000) clean room.

Inspection & Testing

- This product was subjected to inspection in accordance with our Standard Inspection Procedures by qualified inspectors and released by the Quality unit.

Product Specifications & Compliance

Registered Trademark: SterilEnz® is a registered trademark of Avantor Fluid Handling LLC.

USP<88> Class VI: All product contact material(s) of this product have been tested to USP protocols and found to comply with the requirements of USP<88> Class VI Plastics, post-gamma, based on USP testing performed.

USP<87> Cytotoxicity: All product contact material(s) of this product have been tested to USP protocols and found to comply with the requirements of USP<87> Cytotoxicity, *In Vitro*, post-gamma, based on USP testing performed.

Animal Origin Statement: The product contact material(s) in this product are certified to be animal-derived component free (ADCF).

ASTM F756-00 Hemolysis: All product contact materials of this product have been tested to determine hemolytic effects on rabbit red blood cells. Exposure of the cells to saline extract of the post-gamma test material did not result in hemolysis.

USP<661> Physicochemical Tests for Plastics: All product contact materials of this product have been tested and found to comply with the requirements of USP <661> Physicochemical Tests for Plastics, based on USP testing performed.

Suggested Autoclave Cycle and Cable Ties: Autoclave 30 minutes, 123°C. Recommended cable tie: Thomas & Betts, TY5242M.

Gamma-Irradiation: This product is gamma irradiation stable up to 50 KGy.

Storage & Shelf-Life

- Storage in original, unopened packaging in dry, moisture-free environment at ambient conditions and away from direct sunlight, is recommended.
- Expiration for this product is shown above.

Certified by:

Quality Assurance

06 OCT 2020

Date