

Certificate of Compliance

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Refer to website for regional contact information.

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Product Name :Ascent FBR 1m2 Bioreactor Consumable w/ LynxConnector

Catalog Number :6974 Manufacture Date : 2022-05-02

Lot ID :25155808 Expiration Date :2023-05-02

Quality System:

Complies with the current version of the ISO 9001 Standard.

BSE/TSE:

Product is not manufactured with materials of animal origin.

Non-Pyrogenic:

All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Sterilization:

Product has been Gamma irradiated

Quality Control:

Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection - Pass

Packaging Inspection - Pass

Leak Test - Pass

ANDREW J (ANDY) FRANKS CMO Quality Manager

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