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Product Name	:Ascent FBR 2.5m2 Bioreactor Consumable		
Catalog Number	:6972	Manufacture Date	:2023-08-01
Lot ID	:27555081		
Expiration Date	:2024-08-01		

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