

Certificate of Quality

Product: Microfiltration PES hollow fiber module for ATFX System (X.X pore size, nominal X.XX m² surface area, polyethersulfone membrane, single use /single autoclave design)

Part Number: XX:XXXXXX

Lot No.: xxxxxx-mm/yy

Date of Manufacture: Month YYYY

Expiration Date: Month YYYY (5 years from date of manufacture)

Materials of Construction

This product has been constructed from the following materials:

Housing	Polysulfone
Potting Material	Polyurethane (change to Epoxy for F10)
Filtration Filter Media	Polyethersulfone (PES)
Netting	Polypropylene (F6, 8 and 10 only)

All fluid path materials of construction meet USP Class VI biosafety requirements and do not contain any substances derived from animal products or are compliant with EMA 410/01 guidelines.

All materials of construction are 100% lot traceable.

Manufactured in the United States of America

Manufacturing Quality Criteria

This product has been manufactured in ISO Class 7 (GMP 10,000) clean room environment.

Manufacturers Lot Release Criteria

The fiber membrane lot was lot sample tested to verify pore-size rating, water flux rate and burst pressure by the manufacturer.

The membrane surface area is within $\pm 10\%$ of the labeled value.

Each filter module has been integrity tested for acceptance in accordance with manufacturer QC procedures.

Quality Assurance Release Criteria

Filters are inspected for conformance to visual inspection criteria listed in QCP-10022.

EXAMPLE

EXAMPLE

Quality Assurance Representative

Date

Document Number: QA-FM-10261-06