

## Certificate of Conformance

Affix Label Here

100kD  
0.5mm, mPES

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

### Product – Hollow Fiber Module

<b>Materials of Construction:</b>	Housing Potting Material Filtration Filter Media	Polysulfone Polyurethane & May Contain UV Epoxy (fluid path) Modified Polyethersulfone (mPES)
<b>Biological:</b>	The fluid path of this single use hollow fiber module has passed USP Class VI (USP <88>) and/or ISO 10993 testing.	
<b>TSE/BSE:</b>	The fluid path of this single use hollow fiber module conforms to European guidance EMA/410/01.	
<b>Endotoxin*:</b>	The fluid path of a representative hollow fiber module is routinely tested in periodic validations for the presence of endotoxin in accordance with current USP Bacterial Endotoxin Test (USP <85>). Aqueous extracts contained < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate test (LAL).	
<b>Particulate*:</b>	The fluid path of a representative hollow fiber module is routinely tested in periodic validations in accordance with current USP Particulate Matter in Injections Microscopic Particle Count Test (USP <788>).	
<b>Irradiation*:</b>	Part numbers ending in 'S' have been exposed to 25-40 kGy of radiation after final packaging.	
<b>Sterility*:</b>	For MicroKros and MidiKros modules with part number C0#-E100-05-S and D0#-E100-05-S, the fluid path of the hollow fiber module has been validated following ANSI/AAMI/ISO 11137 guidelines for $VD_{max}^{25}$ to provide a minimum Sterility Assurance Level (SAL) of $10^{-6}$ for an established irradiation dose.  Each module with a label denoting a Media/Rating of mPES-P/100kD and mPES-PH/100kD is exposed to 25-40kGy of gamma irradiation after final packaging but is not validated to be considered sterile in accordance with the $VD_{max}^{25}$ method indicated above.	
<b>Testing:</b>	The fiber lot(s) used in the module was sample tested to verify product claims. % Pore Passage (BSA) $\geq 75\%$ % Pore Retention (IgG) $\geq 80\%$ Water flux (L/m <sup>2</sup> /h/psi) $\geq 80$  Each filter module passed integrity testing and visual inspection in accordance with Repligen Quality procedures. Each filter membrane surface area is true within $\pm 10\%$ of the surface area labeled on the filter.	
<b>Shelf Life:</b>	Intended for Single Use within three (3) years for irradiated and five (5) years for non-irradiated, from the date of manufacture.	
<b>Manufacturing:</b>	Repligen is an ISO 9001 certified company and products are manufactured in ISO Class 7 cleanroom meeting Repligen's quality management system requirements. Manufactured in the United States of America. All materials of construction are 100% lot traceable.  Note: The modules with suffix <b>P</b> are assembled in Rancho Dominguez, CA, USA facility in ISO 7 cleanroom meeting ISO 9001 requirements with Hollow Fiber manufactured in France and supplied to Repligen. The X06 modules with suffix <b>PH</b> are assembled in France meeting Repligen QMS requirements. The final finishing and testing is completed in Repligen Rancho Dominguez, CA USA facility.	
<b>Storage:</b>	Store in original packaging at ambient conditions protected from moisture, extreme temperatures, and light.	

\*This is not applicable for modules with part number ending in '-N' or '-P'.

### Issued by Quality Assurance

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