

BPOG Supplier Project Status Reporting June 2019

This information was updated in June 2019

Product Type	Assembly or component family	Representative part number	Status	Target date	Material of construction	Pretreatment	How to obtain
Bag	Wave Cellbag bioreactor bags, mixer bags	CB0002L11-01	Film complete (Bioclear 11) Ports complete	N/A N/A	EVA / Polyolefin Polyolefin	Gamma	Film: Validation guide Cellbag Bioreactors and M*bag mixing bags with Bioclear™ 11 film Ports: Available on request: RegulatorySupportPS@ge.com
Bag	Wave Cellbag bioreactor bags	CB0010L722-01-05PK	Film complete (Fortem) Ports complete	N/A N/A	Polyolefin Polyolefin	Gamma	Validation guide Fortem™ film Ports: Available on request: RegulatorySupportPS@ge.com
Bag	XDR bioreactor / fermentor bags, mixer bags	888-0356-C	Films complete (PL-01026/PL-01077, ReadyKleer) Impellers complete	N/A	Polyolefin Polyolefin / Polycarbonate	Gamma	Validation Guide Xcellerex XDA disposable assemblies
Bag	Ready Circuit storage bags	12410218	Film complete (ReadyKleer) Ports complete	N/A	Polyolefin Polyolefin	Gamma	Validation guide ReadyCircuit Ports: Available on request: RegulatorySupportPS@ge.com
Bag	HyClone liquid media and buffer bags	N/A	Films complete (CX5-14, Aegis5-14)	N/A	Polyolefin	Gamma	Available on request: RegulatorySupportPS@ge.com
Column	ReadyToProcess column housing ≤ 359 mm	N/A	Complete	N/A	Polyolefin	N/A	Validation guide ReadyToProcess columns
Column	ReadyToProcess column housing ≥ 450 mm	N/A	Complete	N/A	Polymethyl-methacrylate	N/A	Validation guide ReadyToProcess columns
Tubing kit	ÄKTA ready Flow Kit	28930182	Complete	N/A	Silicone	Gamma	Available on request: RegulatorySupportPS@ge.com
Tubing kit	ÄKTA readyflux Flow Kit	29187383	Complete	N/A	Thermoplastic elastomer	Gamma	Validation guide ÄKTA readyflux Flow Kit
Tubing kit	ÄKTA ready XL Flow Kit	29264593	Complete	N/A	Silicone	Gamma	Available on request: RegulatorySupportPS@ge.com
Hardware system	ÄKTA Pilot 600	29274328	Complete	N/A	Polyolefin	Cleaning in place (CIP)	Bioprocess Hardware - Extractables Summary ÄKTA Pilot 600
Aseptic connector	ReadyMate DAC	28936688	Complete (lot#1)	N/A	Polycarbonate	Gamma & Autoclave	Available on request: RegulatorySupportPS@ge.com
Tubing	C-flex tubing	N/A	In progress	Q4 2019	Thermoplastic elastomer	Gamma	N/A
Tangential-flow filter	Ultrafiltration hollow fiber filter	UFP-10-E35	In progress	Q4 2019	Polysulfone	CIP	N/A
Tangential-flow filter	Microfiltration hollow fiber filter	RTPCFP-2-E-8S	Not started	Q2 2020	Polysulfone	Gamma	N/A
Tangential-flow filter	Ultrafiltration hollow fiber filter	RTPUFP-500-C-35S	Not started	Q4 2020	Polysulfone	Gamma	N/A
Tangential-flow filter	Microfiltration hollow fiber filter	CFP-1-D-5A	Not started	Q2 2021	Polysulfone	Autoclave	N/A