

FAT Binder Matrix

Summary of factory acceptance test documentation for cell therapy applications

Binder Element	CO ₂	Cent	CRF	Description	Value to GMP customer
Product support					
Design qualification DQ (Technical Data Sheet, drawings)*				Basic spec descriptions of the product an may include some summary drawings	Helps customers choose product and also define installation requirements
Recommended customer maintenance schedule				Vendor-supplied customer-based maintenance & schedule	Helpful to create time based plan for maintenance and audits
Consumables and customer replaceable parts				Replaceable parts based upon usage or wear	Keeps system up and running with proper attention and scheduling
Recommended cleaning procedures				Effective and typical procedures to keep product clean	Avoids any possibility of contamination
Regulatory and Compliance					
Declaration of conformity with EU laws (CE)				CE certificate proof	Attest to the quality level and specification achievements
CSA Certificate				CSA certificate proof	Attest to the quality level and specification achievements
UL Certificate				UL certificate proof	Attest to the quality level and specification achievements
Certificate of Environmental Status				Regulatory certificates for various sustainability items	Shows compliance to the very dynamic environmental regulations
Quality Management System [QMS] Certificate				Factory/site based Quality system description	Provides evidence of adequate quality procedures and compliance
REACH Statement				Regulatory certificates for various sustainability items	Shows compliance to the very dynamic environmental regulations
DIN EN12469 TUV Certification				Regulatory compliance certificate	Well established clean room and airflow standard
DIN ISO 14644-1 Cleanroom compatibility certificate				Regulatory compliance certificate	Well established clean room and airflow standard

* These documents are available from the factory prior to purchase upon request (in addition to drawings)

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Traceability/Validation					
Certificate of Conformance				Production certificate	Proves product made according to specifications
Factory Acceptance Test Report [FAT]				End of Line test summary with checklist of performance	Important to verify product has passed test at Factory level before shipment
Key Material of Construction Specifications				Technical specifications	Proof of specs such materials, surface finish , etc
Steris VHP compatibility certificate				Test certificate for Vaporized Hydrogen Peroxide cleaning	Defines ability to undergo VHP cleaning
Particle Emission Certificate				Test certificate defining particle emissions of product	Enables customer to comply with their clean room particle levels
Porton Down Certificate				Test certificate for centrifuge rotor biocontainment	Proves bio-hazard level containment
HEPA Filter Certificate				Certificate of filter performance	Required to show proper clean room filtration
Temperature Sensor Calibration document				Certificate from supplier on calibration	Proof of calibration
RH Sensor Calibration Document				Certificate from supplier on calibration	Proof of calibration
CO ₂ Sensor Calibration document				Certificate from supplier on calibration	Proof of calibration
CO ₂ Valve certificate of compliance				Certificate from supplier on calibration	Proof of calibration
Certificate of electro-polishing				Material Certificate of surface finish	Proof of cleanability levels and porosity

Color Denotes Serialized Documents

CTS Series

CO₂ = Thermo Scientific™ Forma™ Steri-cult™ CO₂ Incubator

CENT= Thermo Scientific™ General Purpose Pro Centrifuge

CRF = Thermo Scientific™ CryoMed™ Controller Rate Freezer

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